United States Court of Appeals for the Federal Circuit

2015-1149

LIFESCAN SCOTLAND, LTD.,

Appellant,

v.

PHARMATECH SOLUTIONS, INC.,

Appellee.

Appeal from the United States Patent and Trademark Office, Patent Trial and Appeal Board, in No. IPR2013-00247

BRIEF OF APPELLANT

Dianne B. Elderkin
Steven D. Maslowski
Jason E. Weil
Akin Gump Strauss Hauer & Feld LLP
Two Commerce Square, Suite 4100
Philadelphia, PA 19103-7013
Phone: (215) 965-1200
Fax: (215) 965-1210

Counsel for Appellant
LifeScan Scotland, Ltd.

CERTIFICATE OF INTEREST

Pursuant to Federal Circuit Rule 47.4, Counsel for Appellant certifies the following:

1. The full name of every party or amicus represented by me is:

LifeScan Scotland, Ltd.

2. The name of the real party-in-interest (if the party named in the caption is not the real party in interest) represented by me is:

LifeScan Scotland, Ltd.

3. All parent corporations and any publicly held companies that own 10 percent or more of the stock of the party or amicus curiae represented by me are:

Diabetes Diagnostics, Inc.; LifeScan, Inc.; Johnson & Johnson.

4. The names of all law firms and the partners or associates that appeared for the party or amicus now represented by me in the trial court or agency or are expected to appear in this Court are:

AKIN GUMP STRAUSS HAUER & FELD LLP: Dianne B. Elderkin, Steven D. Maslowski and Jason E. Weil

PATTERSON BELKNAP WEBB & TYLER LLP: Gregory L. Diskant and Kathleen M. Crotty

Dated: March 23, 2015

By: /s/Dianne B. Elderkin
Dianne B. Elderkin

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STATEMENT OF RELATED CASES

In *LifeScan Scotland, Ltd. et al. v. Shasta Technologies, LLC, et al.*, Civil Action No. 3-11-cv-04494 (N.D. Cal. filed Sept 9, 2011), Pharmatech and its corporate parent are accused by LifeScan of infringing U.S. Patent No. 7,250,105 (the "105 Patent"). On November 4, 2013, on grounds of patent exhaustion, this Court reversed a District Court's decision granting a preliminary injunction under the 105 Patent. *LifeScan Scotland, Ltd. v. Shasta Techs., LLC*, 734 F.3d 1361 (Fed. Cir. 2013). Claims in the case concerning the 105 Patent are stayed pending this appeal.

In *LifeScan, Inc. et al. v UniStrip Technologies, LLC*, Civil Action No. 3-14-cv-00274 (W.D.N.C filed May 28, 2014), the LifeScan parties allege infringement of two patents, including the 105 Patent. The District Court case is stayed pending resolution of this Appeal.

Currently pending before this Court, in *Ethicon Endo-Surgery, Inc. v. Covidien LP*, No. 2014-1771 (Fed. Cir. appeal docketed Aug. 28, 2014), is the issue of whether the America Invents Act permits the Board to render a final decision in an *inter partes* review where the Director did not institute the review. A decision of this issue in *Ethicon Endo-Surgery* could affect the outcome of this appeal.

JURISDICTIONAL STATEMENT

This appeal arises from the final written decision of the Patent Trial and Appeal Board ("Board") in *inter partes* review No. IPR2013-00247. LifeScan Scotland, Ltd. ("LifeScan") filed a notice of appeal on October 2, 2014, within the time limit specified by 37 C.F.R. § 90.3(a)(1). This Court has jurisdiction over LifeScan's appeal under 28 U.S.C. § 1295(a)(4)(A).

STATEMENT OF ISSUES ON APPEAL

1. Did the Board err in concluding that Pharmatech proved the 105 Patent's claims are invalid for obviousness when, *inter alia*,:

   a) Pharmatech failed to introduce substantial evidence that the prior art references disclosed or suggested every element of the claims or the critical arrangement of those claim elements, and the only evidence of record is LifeScan's contrary evidence;

   b) Pharmatech failed to introduce substantial evidence that a skilled artisan would have been motivated to combine the references, and the only evidence of record is LifeScan's contrary evidence; and

   c) the Board erred in its nexus analysis when considering objective indicia of nonobviousness and accordingly failed to consider undisputed evidence showing copying of the claimed invention?

2. Did the United States Patent and Trademark Office contravene the America Invents Act by allowing the Board, rather than the Director or her proper delegate, to institute the *inter partes* review proceeding?

INTRODUCTION

LifeScan appeals from a final written decision in an *inter partes* review ("IPR") before the United States Patent & Trademark Office ("PTO") Patent Trial and Appeal Board ("Board") in favor of Pharmatech, Inc. ("Pharmatech") holding all three claims of LifeScan's U.S. Patent No. 7,250,105 (the "105 Patent") invalid as obvious.

The 105 Patent is directed to a combination of a disposable test strip design and a measurement method that addresses the problem of ensuring accuracy in blood glucose measurements. The 105 Patent claims a method using a specially configured, disposable test strip having two working electrodes that are used to make independent measurements of electric current, proportional to the concentration of glucose in a blood sample. Those measurements are then compared to one another and, if the difference between them is greater than a predetermined threshold, an error message is given. This invention mitigates accuracy problems that can otherwise arise when insufficient blood sample is applied to the test strip or when there are unrecognized manufacturing problems with the test strips.

The Board initiated and decided the IPR on the basis of Pharmatech's Petition, which presented only conclusory testimony about the disclosures of three prior art references—Nankai, Winarta, and Schulman—and *no* evidence that one

skilled in the art would have been motivated to combine the purported teachings of those references. To fill the gaps in Pharmatech's scant evidence and argument, the Board made erroneous fact findings not proposed by Pharmatech and unsupported by the record. But an IPR is an adjudicative proceeding in which the Board's role is to determine whether *Pharmatech* met its burden of proof, not an examinational proceeding in which the Board can unilaterally review the record and arrive at its own opinions irrespective of Pharmatech's burden.

Compounding its errors, the Board disregarded undisputed evidence that Pharmatech copied the invention of the 105 Patent in developing generic blood glucose test strips that it sells for use with LifeScan meters which carry out the claimed method. The result is a decision based on an incorrect application of the burden of proof, and resulting fact-findings that are unsupported by substantial evidence.

The Board's systemic errors leading to its flawed decision resulted from an IPR proceeding that was initiated by persons not authorized to do so under the relevant statutes. Pursuant to the America Invents Act, the responsibilities for initiating and for conducting IPR proceedings are divided between the PTO Director, on the one hand, and the Board, on the other. Here, the Board made both the decision to institute the IPR and the final decision in the IPR. Because of this

lack of separation, the Board was predisposed to confirm its institution decision, leading it to numerous errors as noted above.

The Board's decision should be reversed.

STATEMENT OF THE CASE

I. THE PARTIES

LifeScan Scotland Ltd. ("LifeScan") is a subsidiary of Diabetes Diagnostics, Inc., which is a subsidiary of LifeScan, Inc. LifeScan, Inc. is one of the Johnson & Johnson Diabetes Solutions Companies that provide advanced products and services to people living with diabetes. LifeScan, Inc. is a world leader in blood glucose monitoring for both home and hospital use.

According to its website, Pharmatech Solutions, Inc. ("Pharmatech") claims to be a "distributor of prescription drug, prescription diagnostics, and home testing products in the United States." See Pharmatech Solutions, http://www.pharmatechdirect.com (last visited March 23, 2015).

II. LIFESCAN'S INVENTION

A. Diabetes/Blood Glucose Monitoring

Diabetes is a disease in which the body manufactures little to no insulin, or improperly utilizes insulin produced, resulting in a build-up of glucose in the blood. A1549. People with diabetes need to frequently measure their blood glucose levels to prevent the chronic complications of high glucose levels and the acute danger of low glucose levels. *Id.* A variety of commercial blood glucose

measurement systems, based on disposable test strips and the electronic meters with which they work, are available to make those measurements. *Id.*

In meter and test strip systems that use electrochemical methods, the test strips contain chemical components that react with glucose in a blood sample to produce a current at an electrode; that current is proportional to the glucose concentration. A1543-44. To measure the electrical current produced by this reaction, there must be at least two electrodes, a "working electrode" at which the reaction that measures the substance of interest is carried out, and a "reference electrode" that is configured to establish a reference point against which the working electrode voltage is established. A1540-41.

To use such a system, the patient inserts a disposable test strip into the meter and then obtains a small drop of blood, usually from a finger, with a lancet. That drop of blood is applied to the strip, and the meter then determines the blood glucose level in the blood by measuring the electrical current produced. Electronic circuitry in the meter converts this measured current to a glucose value that is displayed by the meter to the user. A1543-44.

Obtaining accurate glucose measurements with these systems is critical because patients adjust their food intake or insulin doses based on the measurements. Inaccurate measurements can have dire results for patients. A1549.

The volume of blood needed for such a blood glucose measurement is another important design consideration. People who use these systems prefer to exude smaller rather than larger drops of blood, and for the very young or those who have had diabetes for many years and have reduced blood flow in the extremities, the extrusion of larger drops of blood is difficult and sometimes impossible. A1565. Thus, systems that utilize the smallest amount of blood sample as possible while ensuring accuracy are greatly desired.

B. LifeScan's 105 Patent

The inventors of the 105 Patent recognized that disposable test strips can give inaccurate results if the electrode on a test strip is not fully covered with blood, or if there is a manufacturing defect in, or damage has occurred to, such electrode. A62 (1:39-64); A1550-51. They also recognized the desirability of minimizing the sample volume required for an accurate test. A62 (2:51-56); A1550-51. With their invention, they sought to achieve greater reliability and accuracy in glucose measurements by providing a way to (1) "ensure that an adequate volume of blood had been introduced to cover the entirety of the working electrode of a test strip," and (2) "ensure the electrodes . . . were not defective due to manufacturing irregularities," while (3) "not increasing the volume of blood required for testing." A1551.

The inventors achieved these goals with the elegant solution of providing on each disposable test strip *two* independent working electrodes at which *two* separate glucose measurements of the same sample could be made, and by placing a common reference electrode upstream of each of the two working electrodes. In addition, they developed a method for using these strips in which the electric current (proportional to glucose) measured at each of the working electrodes is compared, and an error is indicated if the difference between the measurements exceeds a predetermined threshold. A1551. A difference greater than the threshold could indicate that not enough blood was introduced to the strip to completely cover the electrodes or that there was a manufacturing defect in one of the electrodes. A1554. Regardless of the cause, an error is indicated to the user rather than presenting a potentially inaccurate glucose concentration value which could have serious detrimental consequences to the user. A1551.

The 105 Patent claims a method for measurement of a substance, such as glucose, in a sample applied to a disposable test strip using an electrochemical system. A64-65 (6:51-8:12). After application of sample to the test strip, electric current is measured between each of two "working sensor parts" relative to a "reference sensor part." A62 (2:3-14, 20-26). The claims recite that the first and second "working sensor part[s]" are "for generating charge carriers [i.e., electrical current] in proportion to the concentration" of the substance being measured and

that the "reference sensor part" is a "common reference" for the first and second working sensor parts. A64-65 (6:55-7:4). In other words, the 105 Patent uses the term "sensor parts" to refer to electrodes.[1] A1550. Because, as will be explained below, this nomenclature can lead to confusion when considering prior art that uses the term "sensor" in a different way, LifeScan uses the term "electrode" hereinafter to refer to the "sensor part" recited in the 105 Patent's claims.

An exemplary embodiment of the disposable test strip design used in the claimed method is depicted in Figure 2 of the 105 Patent, an annotated copy of which is reproduced below (labels indicating Blood Flow and identifying sensors added). Shown are the reference electrode (on Element 4b) referred to as a "reference/counter sensor part" A63 (4:44-45) and two working electrodes where current measurements are made (on Elements 6b and 8b). *Id.* (4:47-50). Each of the working electrodes is connected through conducting connectors (Elements 6a and 8a) to separate current measuring circuits in a blood glucose meter. A1552.

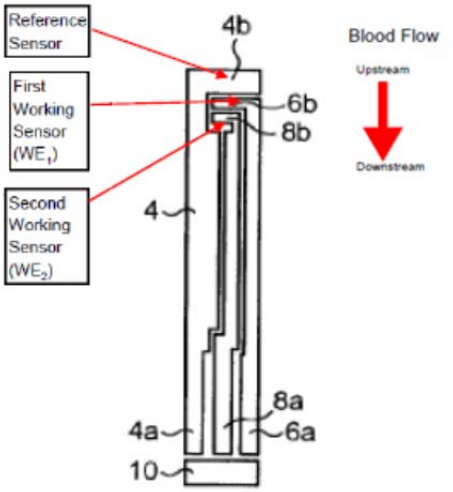


FIG. 2

[1] Pharmatech acknowledges that each "sensor part" in the patent claims is an electrode. A1610.

When a drop of blood is applied to the distal end of the test strip (at the top of the strip as depicted in Figure 2), it flows along the channel in the strip, flowing across the electrodes on elements 4b, 6b, and 8b (*i.e.*, the reference electrode and then the two working electrodes) in that order. A1554. Per the claimed method, the amount of current flowing in the two circuits connected to the two working electrodes is then measured. If the difference between the two measurements is greater than a threshold value, the system reports an error condition. *Id.* If the difference between the currents measured from the two working electrodes is less than the predetermined threshold, the mean value of the currents is converted to a displayed glucose level by the measuring device. *Id.*; A63-64 (4:7-13; 5:26-33). Because of the specific configuration of the test strip and the method by which two measurements of the same sample from the same strip are compared to determine if an error condition exists, greater accuracy of blood glucose measurements is achieved by testing a single sample.

C. LifeScan's One Touch Ultra System

LifeScan's One Touch® Ultra® Systems are the market-leading blood glucose monitoring systems in the United States. A1093. They use the dual-measurement method claimed in the 105 Patent, and this "Double Sure Technology" represents a key advantage over competitor systems. *Id.*; A1596-97. Pharmatech sells generic test strips for use with Ultra meters and admits that it

copied LifeScan's strip design so that its strips can be used in the Ultra system. A1594-97; A1367 (56:20-22).

D. Claims 1-3 Of The 105 Patent

Although Claims 1-3 are method claims, the "providing" step recites a "measuring device"—specifically, as recited in the last subpart of the "providing" step, a "disposable test strip"—having specific elements in a specific configuration. A64-65 (6:54, 7:11). For the purpose of this brief, those claim elements are referred to as the "test strip elements," and the remaining claim elements ("applying," "measuring," "comparing," "giving") are referred to as the "method elements."

E. The Prior Art

None of the prior art relied upon by the Board taught the invention claimed in the 105 Patent or provided the benefits that the claimed method provides. The prior art falls into two categories, prior art applied to the test strip elements and prior art applied to the method elements.

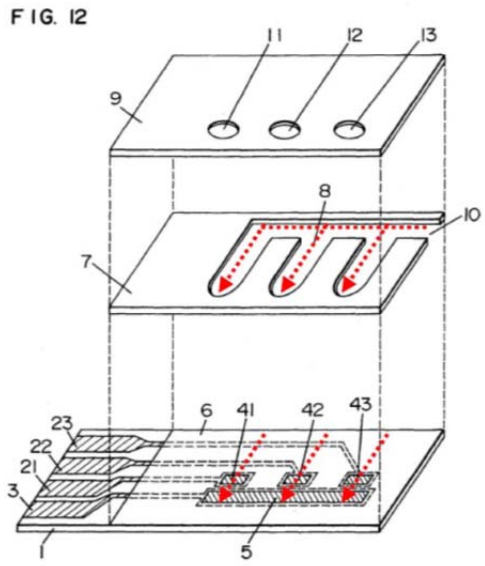
1. "Test Strip" Prior Art

The Board relied, independently, on two patents, Nankai and Winarta, in reference to the test strip elements of the claims. However, neither discloses or suggests the test strip elements claimed in the 105 Patent.

(a) Nankai

Nankai, A130-55, describes disposable biosensors for measuring, for example, glucose concentration in blood. A145 (3:65-68). This reference was considered extensively by the PTO before it issued the 105 Patent. A1439-40; A450-51.

The Board's discussion of Nankai centered on Nankai Figure 12, an annotated copy of which is reproduced to the left (red arrows added to depict blood flow). Figure 12 shows a glucose sensor having a base plate on which is formed counter electrode 5 and measurement electrodes 41, 42, and 43. A147 (8:5-11). Spacer 7 overlies the base plate, and space 8, cutout from the spacer, provides a conduit for blood sample to flow. *Id*. (8:15-19). The measurement electrodes 41, 42 and 43 are coated with glucose oxidase. A146 (5:1); A147 (8:11-14). During use, blood enters through the introducing port and flows along the main conduit of space 8, with portions of the sample entering successive branches along the main conduit. A147 (8:25-29). A current measurement is made at each sensor, and the measurements are averaged to give a final result. *Id*. (8:42-46).



Nankai places the reference electrode 5 downstream from working electrodes 41, 42 and 43, failing to disclose or recognize the criticality of the reference electrode being upstream from the working electrodes, as required by the 105 Patent's claims. A1561-62. As a result, if insufficient blood is applied to the Nankai device, it will be the downstream reference electrode 5 rather than a working electrode 41, 42 or 43 that is incompletely covered. *Id.* Coverage of a minor portion of the reference electrode could cause a higher than normal current density to flow in the covered part of the electrode, altering the ability of the reference electrode to provide a stable potential against which the working electrode could be established and potentially causing inaccurate measurements of glucose. *Id.* Thus, upstream placement of the reference electrode is critical. *Id.*

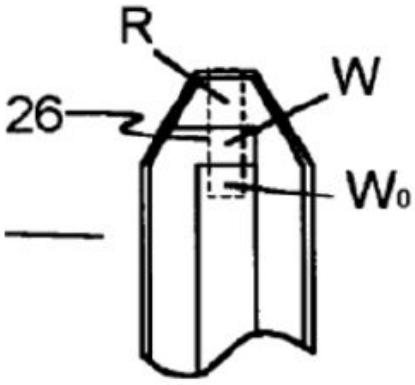
Nankai does not disclose making multiple, independent glucose measurements and comparing the difference between them to an established threshold, as required by the 105 Patent's claims. A1562-63. If there is a manufacturing defect of the Nankai strip, or if an insufficient amount of sample is introduced, an inaccurate result could be measured at any one of the multiple electrode areas. *Id.* If the current measured at one of the Nankai working electrodes is significantly different from that measured at another of the working electrodes, Nankai does not give an indication of error; instead, it just averages all of the readings, even inaccurate ones, and reports the resulting "average" to the

user. *Id.*; A147 (8:42-46). In that case, Nankai's use of the resulting average of the three electrodes would be less accurate than one, completely covered single electrode. A1563. Thus, Nankai's strip and "averaging" method do not address the issue of improving accuracy by ensuring that sample covers the electrodes or by dealing with the problem of potential electrode defects. Nankai does not teach or suggest the novel solution that the 105 Patent teaches and claims.

(b) Winarta

Winarta, A253-66, discloses a disposable test strip for measuring blood glucose. The Board's discussion of Winarta focused on Figure 2, detail of which is reproduced below.

The detail from Figure 2 shows the tip of a test strip. Reference electrode R, working electrode W, and pseudo-working electrode W_0 are positioned in electrode area 26. A262 (5:37-40); A264 (9:4-5). A fluid channel runs over the electrodes, and the electrodes are arranged so that fluid entering the strip flows first over R, then W, and then W_0. A262 (5:59-64). Flow onto W_0 causes a current that triggers a meter to begin a measurement. *Id*. (5:64-66).



Like Nankai, Winarta fails to teach or suggest critical elements of the 105 Patent's claims. The claims require that there be two working electrodes, each of

which generates charge carriers (electric current) in proportion to the concentration of substance (such as glucose) being measured. Winarta only discloses one electrode at which a measurement of glucose is made, working electrode W. With respect to electrode W_0, Winarta discloses three possible utilities for it—(1) as a "counter electrode," (2) to measure resistance, or (3) as a trigger—none of which is as a "working" electrode. A262 (5:64-6:10); A1567-73.

When W_0 is a counter electrode, it is included as part of a three-electrode system to assist in making a single glucose measurement at a *different*, actual working electrode. A262 (6:1-5); A1541-42; A1568-69. When W_0 is used to measure resistance of the sample fluid, it is used to correct for hematocrit interference. A262 (6:5-10); A1569-70. And when W_0 is used as a trigger, it is used to trigger the reading meter to start the measurement and glucose concentration determination process. A262 (5:64-66); A1567; A1570-73. Not only is there no disclosure or suggestion in Winarta of making a glucose measurement at W_0, Winarta fails to suggest any external circuit arrangement or calculation method that would even allow for measurement of a current at W_0 corresponding to glucose concentration. A1570-73.

Since Winarta does not disclose two working electrodes, it also fails to disclose other elements required by the 105 Patent's claims, namely the claimed reference electrode that is upstream of two working electrodes, and the method of

comparing independent current readings from two working electrodes to a threshold for determining error. A1573.

In short, Winarta does not teach or suggest the novel solution for avoiding erroneous glucose measurements that the 105 Patent teaches and claims.

2. Method Prior Art—Schulman

The Board relied on Schulman, A280-305, as allegedly disclosing the "method" elements of the 105 Patent's claims—the "applying," "measuring," "comparing" and "giving an indication of an error" steps. But Schulman is directed to a completely different system than the disposable test strip system recited in the 105 Patent's claims.

Schulman includes at least one "sensor" adapted to be implanted into the patient for continuous glucose monitoring. A293, (2:45-60). When such a sensor is implanted in either tissue or a blood vessel, multiple measurements are made over several days with the same sensor. A1547. "Because multiple measurements are required, a different approach is used to measure glucose than is used with meters and disposable [one-use] test strips as recited in the 105 Patent's claims." *Id.*

Schulman uses the term "sensor" in a different way than the 105 Patent, and its disclosure can be misconstrued if this distinction is not appreciated. A1574-75. As explained above, the invention in the 105 Patent includes a "first working

sensor part" and a "second working sensor part" and a "reference sensor part," where each of these "sensor parts" is an individual electrode on a single disposable test strip. A64-65 (6:51-8:12). In Schulman, a single "sensor" is not an individual electrode but an *entire assembly* that includes multiple electrodes. For example, Schulman describes "glucose sensor 52" which "includes at least three electrodes: a first working electrode W1, a counter electrode C, and a reference electrode R." A296 (7:25-32); A1574-75.

Schulman discloses that measurements can be made from a "plurality of sensors" whose measurements can be compared to look for problems in calibration or function, A1584; A298 (11:7-12), but when it refers to using a "plurality of sensors" to make such measurements, it is referring to using a plurality of *individual assemblies of multiple electrodes* to make multiple measurements—not using a plurality of working electrodes on a single measuring device to make two independent measurement as required by the 105 Patent's claims. A1585. The measurements made by separate "sensor" systems in Schulman are made at different locations (spaced apart 0.4 to 1.0 inches (A297 (10:9-16))), and do not address inaccuracies in glucose measurement on a single test strip. A1585. Schulman's "multiple sensor" teaching is the equivalent of using multiple, separate, disposable test strips to make duplicate measurements, from multiple blood samples, at different locations. A1585.

III. PROCEEDINGS BEFORE THE PATENT AND TRADEMARK OFFICE

A. Pharmatech's Petition

In its Request for *Inter Partes* Review of the 105 Patent, Pharmatech contended that the 105 Patent's claims should be cancelled based on any of thirteen different grounds, including the combinations of Nankai plus Schulman or Winarta plus Schulman. A66-125. As purported evidentiary support for its positions, Pharmatech presented the Declaration of Dr. Joseph Wang who opined that the claims were invalid as obvious. A500-27; A900-943. Dr. Wang provided no definition of the level of ordinary skill in the art and did not state or suggest that he was rendering his opinions from the perspective of one of ordinary skill in the art at the time of the invention, rather than as an expert with hindsight benefit of knowledge of the invention.

Dr. Wang relied on the Nankai and Winarta patents, independently, in support of his opinion regarding the test strip elements of the 105 Patent's claims. A509-10; A520-21. Apparently recognizing (but never stating) that Nankai does not explicitly disclose the claimed test strip configuration in which a reference electrode is upstream from two working electrodes, Dr. Wang asserted—incorrectly and without any explanation—that there was "no benefit or unexpected result" for placing the reference electrode upstream of both working electrodes. A509. With respect to Winarta, he suggested—also incorrectly and without any

explanation— that Winarta's W_0 was a working electrode and that the Winarta test strip was "capable" of taking multiple measurements, using the W and W_0 electrodes as working electrodes. A520-21.

Dr. Wang relied on Schulman in support of his opinion on the method elements of the 105 Patent's claims. A510; A520-21. He stated that Schulman taught using multiple measurements to identify error and asserted, without any support, that incorporating this into Nankai or Winarta would be nothing more than "use of a known technique to improve similar devices/methods in the same way." A510; A521. He did not address the significant differences between the Nankai/Winarta test strip methods and the completely different technology of the Schulman method, in which a sensor is awash with blood and continuously measures glucose. Moreover, he never explained why one skilled in the art would have been motivated to combine the teachings of these disparate references. A509-10; A520-21.

B. LifeScan's Preliminary Response

Pursuant to 37 C.F.R. § 42.107, LifeScan filed a Preliminary Response. A998-1038. LifeScan explained that each of the thirteen reference combinations cited by Pharmatech lacked material claim elements and failed to present a reasonable likelihood that the 105 Patent's claims were obvious. It explained that neither Nankai nor Winarta discloses or suggests, as required by the claims, either

a disposable test strip having two working electrodes downstream from a reference electrode or the method steps of making two glucose measurements from a single test strip and comparing the measurements to make an error determination. A1016-22.

LifeScan also explained that, rather than disclosing a single-use, disposable test strip system, Schulman discloses a very different implantable system for making continuous measurements over a period of time, and that Pharmatech had not presented any evidence for why a skilled artisan would have combined the test strip prior art with the method prior to arrive at the claimed invention. A1031; *see also* A1023-25; A1027-32. Although Pharmatech bore the burden of proving a reasonable likelihood of proving the claims invalid, its declarant, Dr. Wang, had offered only the conclusory statement that allegedly using steps from Schulman with test strips from Nankai or Winarta "would be nothing more than the use of a known technique to improve similar devices/methods in the same way, and the results would be predictable." A510; A521; A1028-29. Dr. Wang offered no explanation for why disposable test strips and implanted, continuous measurement devices would be "similar devices" and no explanation for why one skilled in the art would have been motivated to combine teachings about such distinct devices. A510; A520-21.

Finally, LifeScan presented objective evidence of nonobviousness—namely, evidence of Pharmatech's admitted copying of the claimed invention—that had been presented in a concurrent litigation, and pointed out that Pharmatech's Petition completely ignored this evidence. A1031-32; A1046; A1080-83; A1093-94; A1283-84; A1296; A1305-06.

C. The Board's Institution Decision

On August 15, 2013, a three member panel of the Board instituted the IPR. A32-51. The panel stated that it was persuaded that Pharmatech had demonstrated a reasonable likelihood that claims 1-3 are unpatentable as obvious over the combination of Nankai and Schulman and over the combination of Winarta and Schulman. A49-50. It denied as redundant all other challenges presented in Pharmatech's Petition. A50.

Nankai. Acknowledging that, unlike the patent claims, Nankai positions its reference electrode downstream of the working electrodes, the Board referred to Pharmatech's argument that there was no criticality in arranging the reference electrode upstream and stated that LifeScan had failed to demonstrate that it would not have been obvious to do so. A42-43.

Winarta. The Board accepted Pharmatech's unsupported argument that Winarta describes W_0 as "capable" of being used to take measurements, but did not explain how it was capable of measuring current proportional to the concentration

of a substance (such as glucose) in a sample, as required by the claims. A47-48. Even though the 105 Patent's claims expressly require that the currents measured at the working electrodes be proportional to the concentration of the substance being measured, the Board then posited that it was "irrelevant" whether a current measurement from Winarta's W_0 electrode would be proportional to glucose. A48.

Schulman. Referring to Schulman, the Board concluded that it disclosed taking multiple measurements "from a single blood sample" and using a comparison of readings to alert a user to an unreliable test. A44; A43-49.

Motivation to combine. The Board never addressed LifeScan's arguments that Pharmatech had presented no evidence why one skilled in the art would have combined either Nankai or Winarta with Schulman, and that the combination was based on hindsight reasoning. Instead, the Board focused on whether the references were analogous art, stating that they were because the systems purportedly each use "the same fundamental technique of measuring GOx[glucose oxidase]-mediated electrical current"—a position never propounded in Pharmatech's Petition (and which LifeScan subsequently showed to be erroneous). A43-44; A1581-82; A1508; A1528.

Copying. The Board made no mention of LifeScan's copying evidence in its institution decision.

D. The "Trial"

1. LifeScan's Patent Owner Response

Following institution, LifeScan presented its Patent Owner Response Pursuant to 37 C.F.R. § 42.120. A1473-1529. For the first time in the proceeding, the rules permitted LifeScan to present new testimonial evidence in direct response to Pharmatech's arguments, which it did in a Declaration from expert Dr. John L. Smith.[2] A1532-1599. Dr. Smith holds a Ph.D. in Analytical Chemistry and has decades of experience designing electrochemical diagnostic instrumentation, including over ten years in research and development of techniques for measurement of blood glucose. A1534-36. He offered a definition of the level of ordinary skill in the art (a definition not disputed by Pharmatech and later adopted by the Board) and offered his opinions from the perspective of such a person. A1537; A8. Dr. Smith testified about the significant differences between the claimed invention and the cited references and about distinctions between the test strip art and the continuous monitoring art.

Nankai. Dr. Smith explained that Nankai does not disclose a test strip configuration in which the reference electrode is upstream of the working

[2] LifeScan presented with its Preliminary Patent Owner Response certain fact and expert testimony previously adduced in litigation, A1039; A1091; A1312, but it was not permitted by the rules to present new testimonial evidence in response to Pharmatech's Petition until *after* the Petition had been granted. 37 C.F.R. § 42.107(c).

electrodes, as required by the claims. A1561. And he explained that, contrary to Dr. Wang's conclusory statement adopted by the Board in its institution decision, placing the reference electrode upstream was critical to ensuring accurate measurements if insufficient blood were applied to the test strip. A1561-62. When an insufficient amount of blood is applied to the strip, the downstream electrode may not be fully covered with blood, and if the downstream electrode is the reference electrode, inaccurate readings will result. A1561.

Winarta. Dr. Smith also explained why Winarta does not disclose using the W_0 electrode to make a second glucose measurement, why it is not "capable" of doing so as the Board had erroneously concluded, and why one skilled in the art would not have modified W_0 to make such measurements. A1567-73. He testified, *inter alia*, that "Winarta does not suggest any external circuit arrangement or calculation method in a device to allow measurement of a current at W0 corresponding to glucose concentration *at any time*." A1572 (emphasis in original).

Schulman. Finally, Dr. Smith detailed the significant distinctions between disposable test strip technology for measuring blood glucose and implantable device technology for continuous measurement of blood glucose, as in Schulman. A1543-49; A1574-86. As he testified:

- ***Schulman does not use a disposable test strip to which liquid sample is applied.*** Schulman discloses a device that is implanted into, and is in continuous contact with fluid in, the body and which provides continuous measurements. A1580.
- ***Schulman is directed to a glucose measurement that is fundamentally different from that used in the 105 Patent's claims.*** Unlike the disposable strips of the 105 Patent, in which a current proportional to the amount of glucose is generated at each working electrode, glucose in the Schulman system is measured from oxygen reduction due to the reaction of glucose in the sample with an enzyme. A1581-82. For the Schulman system to give results for a single measurement of glucose, two electrodes capable of measuring oxygen must be present at two locations in the body—one near the point at which the oxygen concentration is reduced by the glucose's reaction with an enzyme and another at a point far enough away so that the background oxygen concentration, not changed by the enzyme reaction, can be measured. A1548. Glucose concentration is calculated by subtracting the reduced oxygen concentration from the background concentration. *Id.*

- ***Schulman does not disclose comparing the electric current from two working electrodes.*** When Schulman refers to a system with two working electrodes, W1 and W2, the second working electrode does not make a glucose measurement; it measures background oxygen. A1577. It is the *difference* between current measurements at this pair of oxygen electrodes that is inversely proportional to glucose concentration; the current measured at either electrode is not itself proportional to glucose concentration. A1548-49. When Schulman describes "a plurality of different sensors" whose measurements can be compared to look for problems in calibration or function, A298 (11:7-22), each of those "sensors" is a completely separate device, each with its own two working electrodes to measure a pair of oxygen concentrations, and each with its own reference and counter electrode. A1584-85. Schulman's comparison of measurements from two sensors, Dr. Smith explained, is equivalent to using two completely separate test strips to make measurements from two blood samples at two locations. A1585.

Motivation to combine. Dr. Smith also explained that, because of the significant differences between disposable test strip systems and continuous measurement systems, one skilled in the art would not have been motivated to

combine the teachings of Schulman and the test strip prior art. A1591; A1589-94. He explained that the Schulman testing paradigm, in which an implanted, frequently calibrated sensor is used multiple times to observe a patient's blood glucose over hours or days, to measure short-term trends, is not related to test strips designed for intermittent measurements at separate times, with each measurement using a new, factory-calibrated test strip. A1586. He explained that the skilled artisan would actually find Schulman teaches *away* from the claimed invention because its continuous-measurement, oxygen electrode system inherently leads to *less* accurate glucose measurements than single measurements from test strips. A1589-94; A1586.

As Dr. Smith explained, from his own personal experience of years of working in development of disposable test strip measurement methods:

> During the 20 years I worked to develop disposable test elements (including more than ten years as chief scientific officer for the world market-leading manufacturer of disposable test strips), because of the great differences in requirements and environments between disposable test strips and implanted sensor assemblies, neither I nor my scientific staff had any motivation to consider how those in-dwelling sensor assemblies operated or were made in order to improve our test strips, or to combine techniques used for those sensor assemblies with disposable test strips.

A1592.

Copying. Dr. Smith also presented further testimony regarding Pharmatech's copying of the claimed invention. He testified about LifeScan's One

Touch® Ultra® meters which measure blood glucose using the method claimed in the 105 Patent and about the generic "GenStrip" test strips that Pharmatech sells for use with the Ultra meters. A1594-97. Pharmatech's GenStrip test strips have the same configuration claimed and illustrated in the 105 Patent, namely, a reference electrode upstream from two working electrodes. *Id.* When Pharmatech's GenStrip test strips are used as intended with LifeScan meters, the method of the 105 Patent's claims is carried out. A1596-97.

Pharmatech has candidly admitted copying LifeScan's patented system. Its outside counsel asserted at a District Court hearing, that "[i]f you want to have a strip that is going to work with the One Touch Ultra system, *you have to copy it*." A1367 (56:20-22 (emphasis added)); A1597.

2. Pharmatech's Reply

Pharmatech filed a brief Reply to the Patent Owner's Response. A1605-20.

Nankai and Winarta. Pharmatech did not reply to LifeScan's evidence on the distinctions between Winarta and the claimed invention. With respect to Nankai, Pharmatech presented the pure-hindsight argument that LifeScan's evidence was allegedly flawed because *the 105 Patent* discloses that "[t]he two working sensor parts may be arranged as convenient." A1607; A1617. It also noted that Nankai stated the arrangement of electrodes may vary. But Pharmatech

presented no substantive response to Dr. Smith's testimony regarding the criticality of the claimed upstream reference electrode. A1607; A1617.

Schulman. Pharmatech focused on Schulman's disclosure of measurement comparisons. A1612. But it offered no response to Dr. Smith's explanation that Schulman compares measurements made by two entirely separate sensor assemblies—the equivalent of comparing glucose measurements made by two entirely different test strips—and does not suggest comparing measurements made by two electrodes on a single test strip as claimed.

Pharmatech's discussion of Schulman in its Reply incorporated and referred to patent figures 1 and 4c that differed—without any explanation—from the actual figures in the Schulman reference. And Pharmatech's discussion of Schulman's disclosure contained citations to columns and lines of Schulman that were unrelated to and did not support the statements being made. *See*, e.g., A1611 (citing A297 (10:30-49), *id.* (10:9-25), A295 (6:50-61), A296 (7:4-5), *id.* (7:50-8:10)). LifeScan brought this problem to the Board's attention at the subsequent Oral Hearing, noting the difficulty for a Patent Owner "to come and defend [its] patent that was issued by the [PTO] in the face of a paper that has citations that make absolutely no sense." A2033-34 (25:11-26:7).

Motivation to combine. Pharmatech conceded that the Schulman and 105 Patent methodologies differ, A1611, but totally ignored Dr. Smith's testimony that

one skilled in the art would not have been motivated to consider disclosures relevant to implantable, continuous monitoring technology in connection with disposable test strip technology.

Copying. Pharmatech did not contest LifeScan's evidence of copying. Instead, it presented only attorney argument, with no citation to record evidence, that the copying evidence was somehow insufficient because the identity of its GenStrip to the test strips claimed in the 105 Patent "is necessary for the Genstrip to work with LifeScan's One Touch Ultra meters that purportedly practice the 105 Patent." A1608; A1619.

E. The Board's Final Written Decision

The Board issued its final decision on August 6, 2014. A1-31. In that decision, authored by the same Panel member who had authored the decision instituting the *inter partes* review and joined by one of the other panel members who had instituted the review, the Board held the claims of the 105 patent invalid as obvious.

1. Claim Construction

The Board construed the relevant claim terms, under the broadest reasonable interpretation standard, as follows:

"Proportion" and "proportional to" were construed as "correlated to." A7.

"Downstream" was construed as "further along a stream from its source." *Id.*

"Substantially unidirectionally" was construed as "along, or nearly along, one direction." *Id.*

2. The Board's Flawed Obviousness Analysis

The Board maintained the position it had espoused in its institution decision that each claim of the 105 Patent would have been obvious in view of either the combination of Nankai with Schulman or the combination of Winarta with Schulman. Even though the statute specifies that the *petitioner* bears the burden of proof in these proceedings, 35 U.S.C. § 316(e), the Board made unsubstantiated and erroneous fact findings never proposed by Pharmatech, to which LifeScan never had an opportunity to respond, and effectively placed the burden on LifeScan to prove validity.

Nankai. The Board acknowledged that Nankai's test strip differs from that recited in the 105 Patent's claims because its reference electrode is downstream of the working electrodes, rather than upstream as claimed. A11. Although there was no evidence of record that Pharmatech's declarant, Dr. Wang, had provided his obviousness opinions from the standpoint of one of ordinary skill in the art, A500-28; A899-943 (he was silent with respect to the level of skill in the art), the Board relied on his conclusory declaration testimony that it was allegedly obvious to

reposition Nankai's electrode/sensor parts to arrive at the claimed configuration. A19 (citing A509). It disregarded LifeScan's unrebutted evidence of the criticality of the claimed upstream reference electrode on a ground that Pharmatech had never raised—and to which LifeScan had never had the opportunity to respond—namely, that LifeScan supposedly had not shown that the criticality of the claimed upstream reference electrode was an *unexpected* result. *Id.*

Winarta. The Board dismissed LifeScan's unrebutted evidence that there is no disclosure in Winarta of using its W_0 electrode as a working electrode as required by the 105 Patent's claims—i.e., as an electrode at which current proportional to the amount of glucose in a sample is generated—and that Winarta therefore does not disclose the test strip elements recited in the 105 Patent's claims. A25. The Board concluded—based again on conclusory, incomplete, and incorrect testimony from Pharmatech's declarant, Dr. Wang—that Winarta describes W_0 as "capable" of being used to take measurements, so that it would have been obvious to modify Winarta to do so. A25-26. The Board incorrectly dismissed the declaration testimony of LifeScan's Dr. Smith, A1571-73, that a glucose measurement *could not be made* at Winarta's W_0 electrode because Winarta fails to suggest any external circuit arrangement or calculation method to allow for such a measurement. A26. Presenting a position for the first time, never propounded by Pharmatech, and to which LifeScan had never had a chance to

respond, and relying on its own, erroneous interpretation of the Winarta reference rather than any expert testimony, the Board stated (incorrectly) that "Winarta does have circuitry for making measurements involving W_0." A26. It then concluded on its own, again with no supporting record evidence, that "the modifications required to the existing [Winarta] circuitry would have been within the ability of one of ordinary skill in the art." *Id.*

Although Pharmatech bore the burden of proving obviousness in the IPR proceeding, the Board deemed LifeScan's nonobviousness unpersuasive because *LifeScan* had not demonstrated that the disclosure in Winarta would have "prevented or dissuaded one of ordinary skill" from considering using the W_0 electrode to measure glucose. *Id.*

Schulman. The Board applied either of Nankai and Winarta in combination with Schulman in support of its obviousness decision, stating that Schulman taught the method steps of comparing independent concentration readings and signaling an error if they diverge. A19-20; A27-28. It dismissed LifeScan's evidence of the significant differences between Schulman's implantable, continuous measurement system and the disposable test strip method of the 105 Patent's claims as being "unpersuasive" because Schulman was not relied on for such disclosures. A15-16. It stated that, instead, Schulman was relied on "only for disclosure of making

multiple measurements and signaling an error if a difference parameter between the measurements exceeds a threshold." A17.

Motivation to combine. The Board cited no record evidence showing that one skilled in the art would have been motivated to combine the teachings of Schulman and the test strip references, even for the limited purpose suggested by the Board. In support of its finding that "one of ordinary skill in the art would have recognized that Schulman's multisensory comparison method could improve the accuracy of Nankai's multisensory test strip," the Board cited to a page of Pharmatech's *Petition.* A14-15. But the attorney argument in Pharmatech's Petition—and even the conclusory declaration testimony of Dr. Wang cited therein—refers only to the alleged result of combining Nankai and Schulman. It says nothing about why one would have been motivated to combine the teachings of those references in the first place.

Lacking any record evidence to show motivation to combine, the Board again turned the applicable burden of proof on its head, concluding that *LifeScan* had not credibly explained "why it would not have been reasonable for one of ordinary skill in the art to have taken away from Schulman only this limited teaching." A17.

Copying. Finally, in dismissing LifeScan's objective evidence of nonobviousness, namely, the evidence of Pharmatech's copying, the Board offered

no disagreement that the undisputed evidence showed that Pharmatech had copied the patented invention. A20-22. Instead, the Board rejected LifeScan's objective evidence as insufficient to overcome Pharmatech's obviousness argument because LifeScan supposedly had not shown a nexus between Pharmatech's copying and the claimed subject matter. *Id.* The nexus, however, is readily apparent—indeed, the court and both parties agreed on the evidence that showed a nexus—the test strips practice the invention, A18; A20, and Pharmatech copied to practice the invention, A1367 (56:20-22); A1608; A1619. Nonetheless, the Board opined that "LifeScan's evidence has not been tied credibly to the claims under review." A22.

SUMMARY OF ARGUMENT

In finding the 105 Patent's claims invalid, the Board erroneously found that all claim elements are disclosed or obvious over the cited references. But Pharmatech bore the burden of proving those claims invalid, and it failed to introduce evidence that one skilled in the art would have found that either the Nankai or Winarta patents suggested the claimed specific, critical arrangement of electrodes on the disposable test strip, or that the Schulman patent suggested the specific, claimed steps of making two current measurements of the same sample and comparing them to identify an erroneous measurement. Similarly, Pharmatech presented no evidence whatsoever showing that a skilled artisan would have been motivated to combine the reference teachings.

Because of Pharmatech's failure of proof, the Board focused on why *LifeScan's* evidence purportedly failed to show nonobviousness, and then came up with justifications never propounded by Pharmatech as to why the references taught the claim elements and why a skilled artisan would have been motivated to combine those purported teachings. In doing so, the Board improperly treated the IPR proceeding as if it were a patent examination rather than an adjudicative proceeding.

LifeScan first learned of the Board's unsupported reasoning in its final written decision. Accordingly, the Board not only ignored the paucity of evidence

presented by Pharmatech and incorrectly shifted the burden to *LifeScan* to *disprove* nonobviousness, but the Board did so in a way that precluded LifeScan from meaningfully addressing the reasoning underlying the Board's decision.

Compounding its error, the Board incorrectly found no nexus between the copying and the claimed invention. But undisputed evidence showed that Pharmatech had copied *the claimed invention*. After LifeScan showed such a nexus, the burden should have shifted to Pharmatech to show it copied for some other reason. The Board failed to shift the burden and accordingly refused to consider evidence of copying.

The Board's flawed decision resulted from an IPR process that violated the relevant statute. The America Invents Act ("AIA"), which created the IPR process, divided IPR decision-making authority between the Director of the PTO and a panel of the Board. Under the statute, the Director must determine whether to institute an IPR, and a panel of the Board must then conduct and decide the merits of any instituted IPR. But there was no such separation here. A three-member Board panel considered evidence from only Pharmatech's expert, issued a decision concluding that Pharmatech had established a "reasonable likelihood" of success on the merits, and instituted the IPR. A three-member panel consisting of two of the same members who made the decision to institute review then conducted the IPR and rendered a final written decision. That decision essentially held that

LifeScan had not changed the panel's mind. This structurally flawed process violated the statute's plain terms and tainted the outcome of the IPR. The Board, after crafting its institution opinion, was predisposed to support that decision, leading it to make the numerous errors noted above.

Pharmatech failed to introduce the evidence necessary to prove the 105 Patent's claims invalid. The Board's decision should be reversed.

STANDARD OF REVIEW

"Whether a claimed invention would have been obvious is a question of law, based on factual determinations . . . ." *Randall Mfg. v. Rea*, 733 F.3d 1355, 1362 (Fed. Cir. 2013). On appeal, this Court reviews the Board's compliance with the legal standards governing obviousness de novo and the underlying factual determinations for substantial evidence. *Id*. Moreover, the Board's action must be set aside when it is "arbitrary, capricious, an abuse of discretion, unsupported by substantial evidence, or otherwise not in accordance with the law." *In re Sullivan*, 362 F.3d 1324, 1327 (Fed. Cir. 2004); 5 U.S.C. § 706(2)(A), (E).

Under 5 U.S.C. § 706, this Court reviews *de novo* all issues of law, including issues of statutory construction. However, where Congress has delegated to the agency the power "to speak with the force of law," *United States v. Mead Corp.*, 533 U.S. 218, 229 (2001), this Court applies the framework

established by *Chevron, U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984).

ARGUMENT

I. THE BOARD ERRED IN FINDING THAT PHARMATECH MET ITS BURDEN OF PROVING THAT THE 105 PATENT'S CLAIMS ARE OBVIOUS

A patent claim is obvious only "if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains." 35 U.S.C. § 103. The Board's ultimate legal conclusion of obviousness must be based on factual determinations including (1) the scope and content of the prior art, (2) differences between the prior art and the patent claims at issue, (3) the level of ordinary skill in the pertinent art, and (4) objective indicia of nonobviousness. *See Randall Mfg.*, 733 F.3d at 1362.

Pharmatech bore the burden of proving that the 105 Patent's claims are invalid. 35 U.S.C. § 316(e). General and conclusory testimony does not suffice as substantial evidence of invalidity. *See Koito Mfg. Co. v. Turn-Key-Tech., LLC*, 381 F.3d 1142, 1152 (Fed. Cir. 2004) (holding expert testimony insufficient where expert did not articulate how the reference anticipates or makes obvious the patent-in-suit); *see also Cytologix Corp. v. Ventana Med. Sys., Inc.*, 424 F.3d 1168, 1176

(Fed. Cir. 2005). Moreover, a challenger's evidence must explain why a skilled artisan would combine specific prior art references "*in the way the claimed invention does.*" *ActiveVideo Networks, Inc. v. Verizon Commc'ns., Inc.*, 694 F.3d 1312, 1328 (Fed. Cir. 2012) (emphasis in original).

A. The Board Erroneously Found That The Prior Art Suggested All Claim Elements

The Board based its conclusion that the 105 Patent's claims are invalid for obviousness, in part, on its finding that Nankai and Winarta each suggested the test strip elements recited in the claims and that Schulman disclosed the method elements recited in the claims. The record does not support the Board's findings as to the scope and content of those references. In fact, in stretching to reach its conclusions, the Board ignored that *Pharmatech* had the burden to prove invalidity and made unsupported and erroneous fact-findings based on its own incorrect reading of the references.

1. Pharmatech Did Not Present Substantial Evidence That Nankai Suggests the Test Strip Configuration Recited in the Claims

Pharmatech did not introduce substantial evidence supporting the Board's finding that the test strip elements of the 105 Patent's claims are suggested or taught by Nankai.

The Board acknowledged that Nankai's test strip differs from the test strip that practices the 105 Patent's claims because its reference electrode is downstream

of the working electrodes, rather than upstream. A11. The upstream position of the reference electrode is one of the critical features of the claimed invention. A1561-62. Nonetheless, in support of its obviousness conclusion, the Board relied on the insufficient testimony of Pharmatech's Dr. Wang that placing the reference electrode upstream, rather than downstream, was obvious to try, A10; A19 (citing A509), and on its incorrect application of an irrelevant line of cases.

A first problem, which affects Dr. Wang's testimony on all issues, is that he never defined the level of ordinary skill in the art and never indicated that he was providing his opinions from the standpoint of one of ordinary skill in the art at the time of the invention, rather than from the standpoint of an expert with present-day, hindsight knowledge of the invention. Although the Board's Decision cites Dr. Wang's testimony as allegedly stating that "*a person of ordinary skill in the art* would have known" that repositioning the reference sensor was obvious to try, A10 (emphasis added), Dr. Wang never offered such testimony. And Dr. Wang could not have testified based on the level of skill proposed (and adopted by the Board) by Dr. Smith, because Dr. Smith's declaration was not yet in the record. The absence of any evidence that a *person of ordinary skill in the art* would have found this invention to have been obvious *at the time of invention* is fatal to Pharmatech's position. *See InTouch Techs., Inc. v. VGo Commc'ns, Inc.*, 751 F.3d 1327, 1352 (Fed. Cir. 2014) ("Not once during [the expert's] direct examination regarding

the . . . patent did she analyze what one of skill in the art would have understood as of 2001.").

Second, Dr. Wang's testimony is tainted by hindsight. He opined that it would have been obvious to try putting Nankai's reference sensor upstream because, he says, *the 105 Patent itself* discloses that "the sensor parts may be arranged in various configurations 'as convenient.'" A509. But Dr. Wang could not have offered this testimony without hindsight knowledge of the 105 Patent. *See Sensonics, Inc. v. Aerosonic Corp.*, 81 F.3d 1566, 1570 (Fed. Cir. 1996) ("To draw on hindsight knowledge of the patented invention, when the prior art does not contain or suggest that knowledge, is to use the invention as a template for its own reconstruction—an illogical and inappropriate process by which to determine patentability.").

Third, Dr. Wang mischaracterized the 105 Patent's disclosure. The patent refers to convenience of various configurations of the *working* electrodes only. A63 (3:36-38) ("The two working sensor parts may be arranged as convenient within the device, or in accordance with the preferred embodiment, on the test member.").

Fourth, Dr. Wang testified that "no benefit or unexpected result is set forth for placing the reference [electrode] upstream of both working [electrodes]." A509. But LifeScan's expert, Dr. Smith, explained that there was indeed a critical

benefit to placing the reference electrode upstream of the working electrodes. A1561-62. If insufficient blood sample were applied to the strip, there was a danger that the electrode farthest downstream would not be fully covered with blood; and if the reference electrode is the farthest downstream, this can lead to inaccurate blood glucose readings. *Id*.

At the same time it incorrectly accepted Dr. Wang's conclusory testimony—which was insufficient under this Court's law—the Board improperly disregarded LifeScan's evidence of the criticality of such an arrangement because LifeScan supposedly had not shown the criticality was unexpected. A12-13 (citing *In re Woodruff*, 919 F.2d 1575, 1578 (Fed. Cir. 1990)); A19. *Woodruff* and its progeny are completely inapposite. Those cases relate to claims directed to a range that was already encompassed within a prior art range (e.g., patentee claims a metal with a thickness of 10-20 mm, and the prior art taught using metal with a thickness of 5-50 mm). In those cases, the claimed range is prima facie obvious based on the disclosed prior art range. *See, e.g.*, *In re Peterson*, 315 F.3d 1325, 1329 (Fed. Cir. 2003) ("In cases involving overlapping ranges . . . even a slight overlap in range establishes a *prima facie* case of obviousness." (citing *Woodruff*, 919 F.2d at 1578)). Those cases are inapposite here; the 105 Patent's claims are not directed to a range, or a range encompassed within a prior art range.

More importantly, on this record the criticality of placing the reference electrode upstream *is* unexpected. It is undisputed that Nankai does not disclose an upstream reference sensor. And when Dr. Wang's conclusory testimony is properly disregarded, Dr. Smith's testimony that upstream placement is critical is also undisputed. If an undisclosed element is shown to be critical, it can only, by definition, be "unexpected." Otherwise, in view of the undisputed criticality, the element would have been disclosed in the art. The undisputed evidence of record shows that the claimed upstream placement of the reference electrode was critical to achieving accurate results—the entire point of LifeScan's invention. The Board failed to consider that evidence because of its incorrect reliance on *Woodruff*. LifeScan's criticality evidence shows the invention is nonobvious and should have been considered by the Board.

There is simply no substantial evidence supporting the Board's finding that the test strip elements of the patent claims would have been obvious from Nankai. For this reason alone, the Board's decision that the claims are obvious over the combination of Nankai and Schulman should be reversed.

2. Winarta Does Not Suggest the Test Strip Configuration Recited in the Claims

As with Nankai, there is no substantial evidence supporting the Board's conclusion that Winarta suggested the test strip elements of the 105 Patent's claims

to one skilled in the art. The Board's finding to that effect was incorrect and unsupported by record evidence.

The challenged claims each require *two* working electrodes, each of which generates current (charge carriers) proportional to the concentration of substance (such as glucose) in a sample, so that the independent glucose measurements made at each of the two working electrodes can be compared to indicate if the measurement is erroneous. Winarta discloses a device with three electrodes, but only one of them, the electrode designated "W," is a working electrode at which a current proportional to the concentration of a substance is generated. A1567-73. The Board's conclusion that the claimed dual-working electrode configuration was nonetheless obvious over Winarta because the disclosed "W_0," electrode was allegedly "capable" of making a glucose measurement, A25, is not supported by the record.

First, there is simply no affirmative evidence in the record that Winarta's W_0 electrode is "capable" of making a glucose measurement. Pharmatech's Dr. Wang made the single, conclusory assertion that the Winarta test strip is "capable of taking multiple measurements (*i.e.*, using the first working sensor part W and the second working sensor part Wo)." A520. But he offered nothing to support this. Dr. Wang's conclusory statement is not substantial evidence. *See Cytologix Corp*, 424 F.3d at 1176. Moreover, Dr. Winarta's assertion is simply wrong. Dr. Smith

explained that Winarta's W_0 electrode is *not* capable of making a glucose measurement, for the specific reason that Winarta fails to suggest the external circuit arrangement or calculation method that would allow for such a measurement. A1571-73.

The Board dismissed Dr. Smith's testimony out-of-hand as "unpersuasive" argument. It did not rely on Pharmatech's evidence, but found the underlying facts based on *its own reading* of Winarta. The Board cited to three lines in Winarta—lines that Pharmatech never cited—as allegedly evidencing that "Winarta does have circuitry for making measurements involving W_0." A26 (citing A262 (6:5-7)). Of course, since this Board "argument" was presented for the first time in its final written decision, LifeScan had no opportunity to present evidence or argument for why it was in error. But even a quick reading of the three lines cited by the Board reveals that they say nothing about circuitry for taking a measurement of the concentration of glucose or another substance at electrode W_0; they refer only to measuring *resistance* at W_0. A262 (6:5-7).[3]

The Board then found that "the modifications required to the existing [Winarta] circuitry would have been within the ability of one of ordinary skill in

[3] In other proceedings before the Board, the Board must affirm or reject an examiner's rejection; the Board cannot enter its own new ground of rejection. *See In re Stepan Co.*, 660 F.3d 1341, 1343-44 (Fed. Cir. 2011) (ex parte reexamination); *Rambus Inc. v. Rea*, 731 F.3d 1248, 1256 (Fed. Cir. 2013) (inter partes reexamination) ("The Board erred when it supplied its own reasons to combine iAPX and Inagaki.").

the art." A26. It did not cite a shred of record evidence to support its finding, and there is nothing in the record to support it. Pharmatech never made that argument, and LifeScan never had the opportunity to respond to it. It is pure conjecture on the part of the Board, and cannot support invalidation of LifeScan's patent.

The Board's final decision reflects that the Board did not render its decision based on whether *Pharmatech* had met its burden of proving that the 105 Patent's claims were invalid. Instead, it treated this as an examinational proceeding in which it was free to make findings that were never proposed by Pharmatech. But 35 U.S.C. § 316(e) unambiguously provides that it is the petitioner who bears the burden of proof in an IPR, and the legislative history for the America Invents Act provisions that culminated in these new proceedings emphasized that they were "adjudicative," and not "examinational." See, H.R. Rep. No. 112-98, at 46-48 (2011) ("The Act converts inter partes reexamination from an examinational to an adjudicative proceeding, and renames the proceeding 'inter partes review.'"); 157 Cong. Rec. S1360, S1375 (daily ed. Mar. 8, 2011) (statement of Sen. Kyl) ("One important structural change made by the present bill is that inter partes reexamination is converted into an adjudicative proceeding in which the petitioner, rather than the Office, bears the burden of showing unpatentability.").

Making things worse, the Board indicated that LifeScan's nonobviousness arguments were somehow unpersuasive because *LifeScan* had not explained why

Winarta's disclosure would have "prevented or dissuaded one of ordinary skill" from using Winarta's W_0 electrode to measure glucose. A26. The Board directly misallocated the burden of proof—LifeScan had no burden to disprove something that was never established in the first place, namely, that a skilled artisan "could have" modified Winarta to practice the claimed invention.

The Board's findings relating to Winarta's disclosure are not based on the record Pharmatech created, and they are replete with legal errors. There is simply no substantial evidence supporting the Board's conclusion that Winarta taught the test strip elements of the patent claims. For this reason alone, the Board's decision that the claims are obvious over the combination of Winarta and Schulman should be reversed.

3. Schulman Does Not Disclose the Claimed Method Steps

Dr. Smith testified about the numerous distinctions between the Schulman continuous measurement method and the patented disposable test strip method. A1586-94. These distinctions were undisputed, and the Board did not question them. Instead, the Board essentially threw up its hands, saying that those distinctions were irrelevant because Pharmatech relied on Schulman "simply for the limited disclosure that multiple measurements of a sample can be made, compared to establish a difference parameter, and rejected if the difference exceeds a threshold." A15. But Schulman does not make that "limited disclosure."

Contrary to the Board's assessment, Schulman does not make and compare "multiple measurements *of a sample*," A15; it takes and compares multiple measurements of a patient's continuously flowing body fluid, at different locations. A1584-85. And those measurements, made by separate electrode systems at different locations in the body, are equivalent to using two separate test strips to measure two blood samples. *Id.* They are not the same as making two measurements of the same sample on a single device—a device designed to accurately perform such a single sample measurement—as claimed in the 105 Patent. *Id.*

Thus, when Dr. Wang conclusorily stated that Schulman "teaches that multiple measurements should be taken to identify errors," A510, or when the Board stated that Schulman was relied on only for disclosure of comparing multiple measurements to determine error, they engaged in high-level cherry-picking from Schulman while ignoring its full disclosure. They ignored that the Schulman testing paradigm is unrelated to that using disposable test strips, and that its continuous-measurement, oxygen electrode system inherently leads to *less* accurate glucose measurements than single measurements from test strip, thereby teaching away from the claimed invention. A1586; A1589-93. The Board was not permitted to selectively choose only the parts of the Schulman disclosure that purportedly supported its conclusion. *W.L. Gore & Assocs., Inc. v. Garlock, Inc.*,

721 F.2d 1540, 1550 (Fed. Cir. 1983), *cert. denied* 469 U.S. 851 (1984) (prior art reference must be considered in its entirety, including portions that would lead away from the claimed invention).

The Board did not find—and there is no evidence to support a finding—that Schulman suggests the method steps of the 105 Patent's claims which include making and comparing measurements of *a single sample* to identify whether that sample accurately reports blood glucose levels. There is therefore no substantial evidence supporting any findings underlying its conclusion that the patent claims would have been obvious over the combination of either Nankai or Winarta with Schulman. For this additional reason, the Board's decision that the claims are obvious over the combination of Winarta and Schulman should be reversed.

B. Pharmatech Failed To Introduce Any Evidence That One Skilled In The Art Would Be Motivated To Combine The References

The question whether there was motivation to combine prior art teachings is a question of fact based heavily on the scope and content of the prior art and the level of skill in the art. *Plantronics, Inc. v. Aliph, Inc.*, 724 F.3d 1343, 1353 (Fed. Cir. 2013). The Board compounded its erroneous findings regarding the prior art disclosures by concluding, in the absence of any supporting record evidence—and in the presence of substantial contrary record evidence—that one skilled in the art would have been motivated to combine the teachings of Nankai or Winarta with those of Schulman.

To prove the 105 Patent's claims would have been obvious, Pharmatech had to introduce specific evidence as to why a skilled artisan would have been motivated to combine the references in the way the claimed invention did. *See ActiveVideo*, 694 F.3d at 1328. In *ActiveVideo*, this Court addressed the type of generic expert testimony that was insufficient to show a motivation to combine:

> The motivation to combine would be because you wanted to build something better. You wanted a system that was more efficient, cheaper, or you wanted a system that had more features, makes it more attractive to your customers, because by combining these two things you could do something new that hadn't been able to do before.

Id. Moreover, Pharmatech was required to introduce evidence as to why a person of skill *would* have combined the references, not just that a person *could* combine them. *InTouch Techs.*, 751 F.3d at 1351-52 (expert's testimony did not provide articulated reasoning for why one would have combined the references). And based on that evidence, the Board was required to make clear the basis in the record for its reasoning. *KSR Int'l Co. v. Teleflex, Inc.*, 550 U.S. 398, 418 (2007); *see also Plantronics*, 724 F.3d at 1354.

Pharmatech's expert Dr. Wang provided no reason why one skilled in the art would have been motivated to combine the references; he provided only the conclusory statement that the combination would be nothing more than "use of a known technique to improve similar devices/methods in the same way." A510; A521. He offered no analysis of why this was so. Pharmatech's generic evidence

that one skilled in the art would be motivated to "improve" a device is no better than the generic evidence rejected in *ActiveVideo*. *See* 694 F.3d at 1328. Indeed, reflecting the generic nature of his testimony, Dr. Wang repeated the same conclusory mantra, word-for-word, in connection with ten of the thirteen different "obviousness grounds" presented in his Declaration. *See*, A508; A510; A515-19; A521-22; A525.

In its final written decision, the Board credited Pharmatech with having presented a motivation rationale "that one of ordinary skill in the art would have recognized that Schulman's multisensory comparison method could improve the accuracy of Nankai's multisensory test strip." A14-15. But Pharmatech never presented such a rationale—the page of Pharmatech's petition to which the Board cites as supposed support for its reasoning says nothing about what those of ordinary skill "would have recognized." A15 (citing A84). Moreover, Pharmatech's record *evidence*, as opposed to any conclusory attorney argument, is silent with respect to what skilled artisans "would have recognized." A509-10; A520-21. No evidence of record supports the Board's fact finding.

Next, the Board tried to justify the lack of Pharmatech's motivation evidence by indicating that *LifeScan* had failed to *disprove* motivation. According to the Board, it relied on Schulman "not for disclosure of the particular glucose measurement method, but rather only for disclosure of making multiple

measurements and signaling an error if a difference parameter between the measurements exceeds a threshold" and that *LifeScan* had not credibly explained "why it would not have been reasonable for one of ordinary skill in the art to have taken away from Schulman only this limited teaching." A17. This, of course, improperly turns the burden of proof on its head. LifeScan had no burden to disprove anything. *Pharmatech* had the burden to prove obviousness, including the burden of presenting an explicit analysis of why there was an apparent reason for skilled artisans to combine elements in the fashion claimed by the patent, which it did not do. *ActiveVideo*, 694 F.3d at 1328.

In sum, Pharmatech's failure to meet its burden of coming forward with evidence and explicit analysis of why one skilled in the art would have combined the alleged disclosure of Nankai/Winarta and Schulman is another, independent reason why the Board's decision that the 105 Patent's claims are invalid should be overturned.

C. The Board Erred In Failing To Consider Copying Evidence

The Board's legal errors did not end with its attempted burden-shifting on the question of motivation to combine. It also erred in failing to credit the independent, undisputed objective evidence of nonobviousness of the 105 Patent's claims, namely, evidence that Pharmatech had expressly copied the claimed invention in designing its GenStrip test strips.

"[C]opying by a competitor may be a relevant consideration in the secondary factor analysis." *Iron Grip Barbell Co. v. USA Sports, Inc.*, 392 F.3d 1317, 1325 (Fed. Cir. 2004). "Whether before the Board or a court, this court has emphasized that consideration of the objective indicia [of nonobviousness] is *part of* the whole obviousness analysis, not just an afterthought." *Leo Pharm. Prods., Ltd. v. Rea*, 726 F.3d 1346, 1357 (Fed. Cir. 2013) (emphasis in original). This evidence is not just a cumulative or confirmatory part of the obviousness calculus, but constitutes independent evidence of nonobviousness. *Ortho-McNeil Pharm., Inc. v. Mylan Labs., Inc.*, 520 F.3d 1358, 1365 (Fed. Cir. 2008) ("Objective indicia may often be the most probative and cogent evidence of nonobviousness in the record." (citation omitted)); *Advanced Display Sys., Inc. v. Kent State Univ.*, 212 F.3d 1272, 1285 (Fed. Cir. 2000) (defendant's "wholesale copying" of claimed invention "provides compelling evidence of nonobviousness). To show a nexus between the objective evidence of copying and the claimed invention, the patentee must show that the challenger (1) actually *copied* the patentee's product, and (2) that product embodies his *invention*, and has the claimed features of his invention. *See Iron Grip Barbell*, 392 F.3d at 1325; *see also Pregis Corp. v. Kappos*, 700 F.3d 1348, 1355-56 (Fed. Cir. 2012).

LifeScan proved, and it is undisputed, that Pharmatech *copied the invention of the 105 Patent's claims* when it designed its GenStrip test strips for use in

LifeScan's One Touch Ultra meters. A1594-97. The Board found that use of either party's test strips falls within the scope of the claims. A18; A20; A1596-97. Pharmatech repeatedly admitted that it copied the test strips to practice the claimed invention. A1367 (56:20-22); A1608; A1619.

The Board erroneously disregarded LifeScan's evidence of Pharmatech's copying because LifeScan's copying evidence allegedly was not "tied credibly to the claims under review." A22. But LifeScan proved that Pharmatech copied the *claimed invention*. A1594-97; A1608; A1619; A1367 (56:20-22). And by proving copying *of the claimed invention*, LifeScan showed a nexus to the claimed invention. *Demaco Corp. v. F. Von Langsdorff Licensing, Ltd*., 851 F.2d 1387, 1392 (Fed. Cir. 1988).

After LifeScan showed that Pharmatech copied the claimed invention, the burden should have shifted to Pharmatech to show that it copied the invention for some reason that does not evidence nonobviousness. *See id.* at 1393 (once patentee shows nexus between objective evidence and merits of claimed invention, burden shifts to challenger to show the evidence does not show that claimed invention is nonobvious); *Crocs, Inc. v. Int'l Trade Comm'n*, 598 F.3d 1294, 1311 (Fed. Cir. 2010) ("In the absence of any record evidence attributing these secondary considerations [including copying] to causes other than the claimed invention, Crocs may rely on this added support for nonobviousness."). A contrary

ruling would impermissibly require LifeScan to prove a negative. *See Demaco Corp.*, 851 F.2d at 1394.

Pharmatech's copying evidences nonobviousness; LifeScan was not required to disprove all other theories. Accordingly, the burden shifted to Pharmatech to show that its copying was for some other reason that did not demonstrate nonobviousness, and it came forward with no such evidence. In fact, the relevant evidence from the mouth of a Pharmatech witness only confirms that its copying was for the purpose of carrying out the claimed invention. The One Touch System carries out the method claimed in the 105 Patent. A18; A1596-97. Pharmatech's outside counsel admitted in trial testimony that "you have to copy" LifeScan's test strip if you want a test strip to work with its One Touch system. A1367 (56:20-22); *see also* A1608; A1619. In copying a test strip to work with that system, Pharmatech admits that it copied in order to carry out the claimed method.

The cases the Board cites, A20-21, do not change this analysis. In *Institut Pasteur v. Focarino*, 738 F.3d 1337, 1348 (Fed. Cir. 2013), the question was simply whether Pasteur presented evidence that could show the first element of the analysis—whether there was actual copying. There, the district court failed to assess whether there were similarities in the methods and access to Pasteur's article describing its invention, which might have shown copying. Similarly, in *Cable Elec. Prods., Inc. v. Genmark, Inc.*, 770 F.2d 1015, 1027-28 (Fed. Cir. 1985), the

patentee failed to show actual product copying. In dicta, the court noted other types of evidence that might show evidence that copying is not actually evidence of nonobviousness, but that analysis was irrelevant to the outcome, and the court did not specify which party should have the burden of introducing such evidence. *Id*. at 1028. And in *Wm. Wrigley Jr. Co. v. Cadbury Adams USA LLC*, 683 F.3d 1356, 1364 (Fed. Cir. 2012), the court noted that the evidence showed Cadbury sought to reformulate its products to match Wrigley's product in numerous non-patented ways, i.e., that Wrigley did not just copy the *claimed invention*.

"Appeals in patent cases should not be mere games played with pieces of paper called references and the patent in suit. Lawsuits arise out of the affairs of people, real people facing real problems." *Rosemount, Inc. v. Beckman Instruments, Inc.*, 727 F.2d 1540, 1544 (Fed. Cir. 1984). Had the Board considered LifeScan's compelling, real-world evidence of nonobviousness, as the law required it to do, it may not have succumbed to the hindsight bias infecting its obviousness analysis. Its error in disregarding LifeScan's copying evidence provides another, independent reason for reversing its invalidity ruling.

II. THE STATUTE REQUIRES THAT THE INSTITUTION DECISION BE MADE BY THE PTO DIRECTOR AND THAT THE PROCEEDING THEN BE CONDUCTED AND DECIDED BY MEMBERS OF THE BOARD

The statute governing *inter partes* review expressly divides decision-making authority between the Director, who institutes review, and a panel of the Board,

which conducts and finally decides the proceeding. Currently pending before this Court is a challenge to the PTO's regulation and procedures that allow the Board to make both the institution and final decisions. *See* Brief of Appellant, *Ethicon Endo-Surgery, Inc. v. Covidien LP*, No. 2014-1771 at 25-43 (Fed. Cir. appeal docketed Aug. 28, 2014) (D.I. 18). Here, as in the *Ethicon* IPR, a panel comprised of overlapping Board members made both determinations. That procedure violated the law and contributed to the errors described above.[4]

A. The Plain Text Of The Statute Prohibits The Board From Rendering Final Decisions Where The Director Did Not Institute Review

In the America Invents Act, Congress set forth statutory requirements providing for the institution and the resolution of IPR proceedings. 35 U.S.C. § 314(b) requires the Director to determine whether to institute review. 35 U.S.C. §§ 6(c), 316(c), and 318(a) require a three judge Board panel to conduct the IPR proceeding and to issue a final written decision based on its review.

[4] LifeScan did not include below its challenge to the Board's non-bifurcated decision-making procedure because the Board is bound by regulation and therefore could not alter its procedure. *See Garcia v. Dep't of Homeland Sec.*, 437 F.3d 1322, 1343 (Fed. Cir. 2006). Moreover, LifeScan was bound to comply with the regulations governing the content of patent owners' filings, which do not provide an opportunity to raise such a challenge. *See* 37 C.F.R. § 42.120. These issues do not fall within the Board's expertise or discretion, and including them would have been futile in light of the Board's inability to address them. *See Beard v. Gen. Servs. Admin.*, 801 F.2d 1318, 1321 (Fed. Cir. 1986).

This Court has already recognized that the AIA creates a divided process between two decision-makers. As this Court explained when deciding whether 35 U.S.C. § 314(d) prohibits appeal of a decision not to institute, "[t]he statute separates the Director's decision to 'institute' the review, § 314, on one hand, from the Board's 'conduct' of the review 'instituted' by the Director, § 316(c), and the Board's subsequent 'written decision,' § 318, on the other." *St. Jude Med., Cardiology Div., Inc. v. Volcano Corp.*, 749 F.3d 1373, 1375 (Fed. Cir. 2014). The decision whether to institute review lies within the discretion of the Director.

The Director may, of course, delegate her authority to institute a requested review, but she must do so consistent with the specific limitations on her delegation authority. *See Touby v. United States*, 500 U.S. 160, 169 (1991). Here, the statute limits the Director's delegation authority to officers whom the Director has appointed. Specifically, the statute authorizes the Director to "appoint . . . officers, employees (including attorneys), and agents," 35 U.S.C. § 3(b)(3)(A), and then provides that the Director may "define the . . . authority . . . of such officers and employees and delegate to them such of the powers vested in the Office," *id.* § 3(b)(3)(B).

The Director does not appoint the Board's administrative patent judges—the Secretary of Commerce does. *Id.* § 6(a). They are beyond the limits of the delegation provision. Accordingly, the Director's attempted delegation of her

decision-making authority to the Board under 37 C.F.R. § 42.4(a) ("The Board institutes the trial on behalf of the Director") is inoperative, as the Director is not authorized by statute to delegate her responsibilities to the Board. The Director's erroneous delegation of the institution decision to the administrative patent judges is particularly problematic where, as here, the Director has also promulgated regulations restricting the patent owner's presentation of evidence at the institution phase. *See* 37 C.F.R. § 42.107(c). The PTO's regulations require the Board to consider a one-sided record to determine whether to institute review, and then require the Board to re-visit that decision in light of the Patent Owner's additional evidence. 35 U.S.C. § 316(a)(8). Delegation of institution authority to the Board violates the statutory IPR scheme, and contributed to the Board's erroneous decision here.[5]

[5] This Court's decision in *In re Cuozzo Speed Technologies, LLC*, holding that "§ 314(d) prohibits review of the decision to institute IPR even after a final decision" does not bar LifeScan's appeal of this issue for at least two reasons. No. 14-1301, 2015 U.S. App. LEXIS 1699, at *8 (Fed. Cir. Feb 4, 2015). First, LifeScan is not seeking review of the institution decision, but rather the final determination, which was the result of a flawed process that was contrary to the statute. Second, § 314(d) does not apply here as the statute by its plain terms only bars appeals of an institution decision made "by the Director." Neither the Director, nor her proper delegate, made the institution decision in this IPR.

B. The PTO's Illegal Procedure Contributed To Its Erroneous Obviousness Determination.

The PTO's IPR procedure was not only contrary to the statute, but contributed to the Board's flawed decision.

The Board's errors here stem from its effort to affirm its institution decision. Notably, the Board rejected *all* evidence submitted after the institution decision—all of Dr. Smith's testimony about the distinctions between the cited references and the claimed invention, about the reasons why those skilled in the art would not have been motivated to combine the teachings of those references, and about the objective evidence of nonobviousness in the form of Pharmatech's undisputed copying of the invention. It then made its own, mistaken interpretations of prior art disclosures to try to fill gaps left by Pharmatech's evidence, and came up with its own flawed reasons for disregarding LifeScan's evidence. Rather than adjudicating whether *Pharmatech* met its burden of proof, the Board erroneously required *LifeScan* to prove why skilled artisans would *not* have modified the prior art to arrive at the claimed invention. The Board substituted its own pre-institution judgment in place of a review of all of the evidence through the lens of Pharmatech's burden of proof—a direct result of the PTO's flawed IPR procedure.

CONCLUSION

The final written decision of the Patent Trial and Appeal Board should be reversed.

Dated: March 23, 2015

Respectfully submitted,

By: */s/ Dianne B. Elderkin*

Dianne B. Elderkin
Steven D. Maslowski
Jason E. Weil
AKIN GUMP STRAUSS HAUER & FELD LLP
Two Commerce Square
2001 Market Street, Suite 4100
Philadelphia, PA 19103-7013
Phone: (215) 965-1200
Fax: (215) 965-1210

Counsel for Appellant
LifeScan Scotland, Ltd.

ADDENDUM

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Trials@uspto.gov
Tel: 571-272-7822

Paper 27
Entered: August 6, 2014

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

PHARMATECH SOLUTIONS, INC.,
Petitioner,

v.

LIFESCAN SCOTLAND LTD.,
Patent Owner.

Case IPR2013-00247
Patent 7,250,105 B1

Before SALLY C. MEDLEY, SCOTT E. KAMHOLZ, and SHERIDAN K. SNEDDEN, *Administrative Patent Judges.*

KAMHOLZ, *Administrative Patent Judge*.

FINAL WRITTEN DECISION
35 U.S.C. § 318(a) and 37 C.F.R. § 42.73(b)

I. INTRODUCTION

A. Background

Pharmatech Solutions, Inc. ("Pharmatech") filed a Petition (Paper 1, "Pet.") to institute an *inter partes* review of claims 1-3 (the "challenged claims") of U.S. Patent No. 7,250,105 B1 (Ex. 1002, "the '105 patent"). We instituted trial for the challenged claims on the following grounds of unpatentability asserted by Pharmatech:

References[1]	**Basis**	**Claims challenged**
Nankai and Schulman	§ 103	1-3
Winarta and Schulman	§ 103	1-3

Decision to Institute 19 (Paper 11, "Dec.").

After institution of trial, LifeScan Scotland Ltd. ("LifeScan") filed a Patent Owner Response (Paper 16, "Resp."). Pharmatech filed a Reply (Paper 17, "Reply"). LifeScan did not file a motion to amend claims.

Pharmatech relies upon a declaration of Joseph Wang, D.Sc. (Ex. 1024) in support of its Petition. LifeScan relies upon a declaration of John L. Smith, Ph.D. (Ex. 2008) in support of its Response.

Oral argument was conducted on May 14, 2014. A transcript is entered as Paper 26 ("Tr.").

We have jurisdiction under 35 U.S.C. § 6(c). This final written decision is issued pursuant to 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73.

[1] The references are: U.S. Patent No. 5,120,420 (Ex. 1003, "Nankai"), U.S. Patent No. 5,791,344 (Ex. 1007, "Schulman"), and U.S. Patent No. 6,258,229 (Ex. 1005, "Winarta").

Pharmatech has proved that claims 1-3 are unpatentable.

B. The '105 Patent

The '105 patent relates to monitoring the level of a substance in a liquid, particularly the level of glucose in blood. Ex. 1002, 1:7-10. A glucose assay is performed by inserting a test strip into a meter and then applying a drop of blood to the test strip. *Id.* at 5:14-25. The test strip is made from layers of various materials, built up on a plastic base and capped with a cover. *Id.* at 4:35-5:14. Figure 2 is reproduced below:

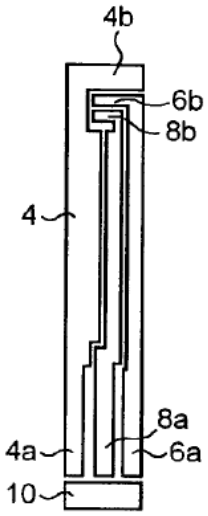


FIG. 2

Figure 2 illustrates one layer of the test strip, in which a pattern of carbon ink is screen-printed onto the test strip base. *Id.* at 4:23-24. The carbon ink forms three tracks 4, 6 (not labeled), and 8 (not labeled), along the strip, as well as a connecting bridge 10. *Id.* at 4:44-51. Each track has a connecting terminal 4*a*, 6*a*, 8*a* at one end of the strip and an electrode 4*b*, 6*b*, 8*b* at the other, distal, end. *Id.* A layer of glucose oxidase ("GOx") is printed on the electrodes. *Id.* at 4:65-66. Various other layers are deposited to define the

rest of the structure, such as the precise sizes of the electrodes and a flow path for the blood. *Id.* at 4:54–5:14.

A user begins a glucose measurement by inserting the terminal end of the test strip into a meter device; the connecting bridge completes a circuit upon insertion to turn on the device. *Id.* at 5:16-18. The device applies a voltage between the reference terminal 4*a* and terminal 6*a,* and also between the reference terminal 4*a* and terminal 8*a*. *Id.* at 5:19-22. A drop of blood is deposited at the distal end of the strip, and the blood is drawn by capillary action over electrode 4*b* for the reference sensor part and electrodes 6*b* and 8*b* for the working sensor parts. *Id.* at 5:23-26. The blood thereby comes into contact with the GOx printed on the electrodes, and the GOx reacts with glucose in the blood to release electrons.

The resulting electric currents through carbon tracks 4 and 6 are proportional to both the surface area of the electrode covered by GOx and the amount of glucose in the blood sample. *Id.* at 1:27-38. Because the GOx surface area is known, the electric current is indicative directly of the amount of glucose in the blood. *Id.* The currents are measured by the meter device after a predetermined time. *Id*. at 5:26-27. The current measurements are compared to one another, and if they differ by more than 10%, an error message is displayed so that the user will know to repeat the test. *Id.* at 5:27-30. If they are within 10% of each other, the measured currents are summed and converted into a glucose level, which is then displayed. *Id*. at 5:30-33. Regarding arrangement of the sensor parts, the ’105 patent discloses that it is “preferred that both working sensor parts are downstream of the reference sensor part.” *Id.* at 3:56-58.

The challenged claims are reproduced below:

1. A method of measuring the concentration of a substance in a sample liquid comprising the steps of:

providing a measuring device said device comprising:

a first working sensor part for generating charge carriers in proportion to the concentration of said substance in the sample liquid;

a second working sensor part downstream from said first working sensor part also for generating charge carriers in proportion to the concentration of said substance in the sample liquid wherein said first and second working sensor parts are arranged such that, in the absence of an error condition, the quantity of said charge carriers generated by said first working sensors part are substantially identical to the quantity of said charge carriers generated by said second working sensor part; and

a reference sensor part upstream from said first and second working sensor parts which reference sensor part is a common reference for both the first and second working sensor parts, said reference sensor part and said first and second working sensor parts being arranged such that the sample liquid is constrained to flow substantially unidirectionally across said reference sensor part and said first and second working sensor parts; wherein said first and second working sensor parts and said reference sensor part are provided on a disposable test strip;

applying the sample liquid to said measuring device;
measuring an electric current at each working sensor part proportional to the concentration of said substance in the sample liquid;
comparing the electric current from each of the working sensor parts to establish a difference parameter; and
giving an indication of an error if said difference parameter is greater than a predetermined threshold.

2. The method as claimed in claim 1 comprising measuring the current at each working sensor part after a predetermined time following application of the sample.

3. The method as claimed in claim 1 wherein the substance to be measured is glucose, and each of the working sensor parts generates charge carriers in proportion to the concentration of glucose in the sample liquid.

II. DISCUSSION

A. Claim Construction

In an *inter partes* review, claim terms in an unexpired patent are interpreted according to their broadest reasonable construction in light of the specification of the patent in which they appear. 37 C.F.R. § 42.100(b); *Office Patent Trial Practice Guide*, 77 Fed. Reg. 48756, 48766 (Aug. 14, 2012). Also, claim terms are given their ordinary and customary meaning, as would be understood by one of ordinary skill in the art in the context of the entire disclosure. *In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257

(Fed. Cir. 2007). Any special definition for a claim term must be set forth in the specification with reasonable clarity, deliberateness, and precision. *In re Paulsen*, 30 F.3d 1475, 1480 (Fed. Cir. 1994).

We construed several claim terms as follows:

1. "Proportion" and "proportional to" as "correlated to" (Dec. 8);

2. "Downstream" as "further along a stream from its source" (*id.* at 8-9); and

3. "Substantially unidirectionally" as "along, or nearly along, one direction" (*id.* at 9).

The parties do not contest these constructions (Tr. 4:9-12, 16:1-21), and we maintain them.

B. Obviousness over Nankai and Schulman

Pharmatech argues that claims 1-3 are unpatentable under 35 U.S.C. § 103(a) over Nankai in combination with Schulman. Pet. 16-21. LifeScan responds, both arguing that Pharmatech has not demonstrated the obviousness of the claims (Resp. 17-21, 26-43), and presenting objective evidence of nonobviousness. Resp. 45-49.

We undertake the four factual inquiries of an obviousness analysis: determining the scope and content of the prior art; ascertaining the differences between the prior art and the claims at issue; resolving the level of ordinary skill in the pertinent art; and assessing objective evidence of nonobviousness. *Graham v. John Deere Co.*, 383 U.S. 1, 17-18 (1966).

1. The level of skill in the pertinent art

"The person of ordinary skill in the art is a hypothetical person who is presumed to know the relevant prior art." *In re GPAC Inc.*, 57 F.3d 1573,

1579 (Fed. Cir. 1995). This person is of ordinary creativity, not merely an automaton, and is capable of combining teachings of the prior art. *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 420-21 (2007).

LifeScan argues that one of ordinary skill in the relevant art is a person having a Bachelor's degree in chemistry or electrical engineering, or an equivalent degree in a related field, such as physics or chemical engineering, and also having five years of experience working in the field of electrochemical glucose sensors. Resp. 13-14 (citing Ex. 2008 ¶ 13). Pharmatech does not dispute this proposed definition. The definition is reasonable, and we adopt it for purposes of this decision.

2. Scope and content of the prior art

a. Overview of Nankai

Nankai describes disposable biosensors for measuring, e.g., glucose concentration in blood. Ex. 1003, 3:65-68. Figure 12 of Nankai is reproduced below:

FIG. 12

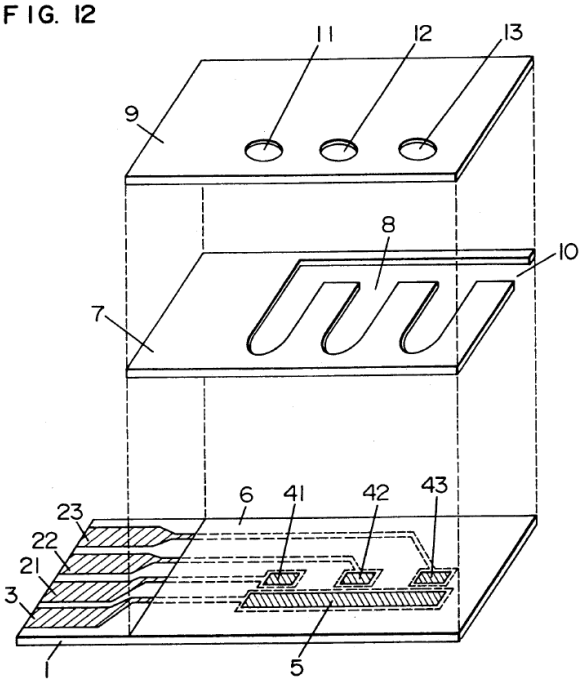


Figure 12 shows a glucose sensor having base plate 1 on which is formed lead 3 and corresponding counter electrode 5, and leads 21, 22, and 23, and corresponding measurement electrodes 41, 42, and 43. *Id.* at 8:5-10. Spacer 7 overlies the base plate, and space 8 cut out from the spacer provides a conduit for a blood sample to flow from introducing port 10 to the measurement and counter electrodes. *Id.* at Abstr., 8:15-18. Cover 9 provides discharge ports 11, 12, and 13, through which air leaves space 8 as it is displaced by the flowing blood. The measurement electrodes are coated with GOx. *Id.* at 5:1, 8:11-14. During use, blood enters through the introducing port and flows along the main conduit of space 8, with portions of the sample entering successive branches along the main conduit. *Id.* at 8:25-27. A current measurement is made at each sensor, and the measurements are averaged to give a final result. *Id.* at 8:42-46. The shape or arrangement of sensors may vary. *Id.* at 8:50-52.

b. Overview of Schulman

Schulman describes an implantable sensor used to monitor blood glucose continuously by GOx-mediated current measurements. Ex. 1007, 3:17-28, 4:20-30, 7:35-37. Two or more sensors may be used to confirm the correctness of the measurement. *Id.* at 4:46-50. The readings from two sensors are compared, and if they are not within 10% of one another, the system requests sensor recalibration (*id.* at 11:16-22, 20:50-54), and issues an error message advising the user to check the sensors. *Id.* at 21:9-13.

3. Differences between the claimed subject matter and the prior art

a. Petitioner's Case-in-Chief

Pharmatech argues that Nankai discloses all limitations of claim 1 except (*a*) the position of the reference sensor part "upstream" of the first and second working sensor parts; (*b*) the step of comparing the electric current from each of the working sensor parts to establish a difference parameter; and (*c*) the step of giving an indication of an error if the difference parameter is greater than a predetermined threshold. Pet. 16-21.

With regard to limitation (*a*), Pharmatech points to Nankai's teaching that the arrangement of the sensors may vary. *Id.* at 16 (citing Ex. 1003, 8:47-52). Pharmatech argues that the '105 patent discloses that the sensors may be arranged "as convenient" and does not identify any benefit or unexpected result from the claimed arrangement. *Id.* (citing Ex. 1002, 3:36-58). Pharmatech cites evidence, from the testimony of Dr. Wang, that a person of ordinary skill in the art would have known that there was a finite number of ways to arrange a reference sensor part in relation to a working sensor part and that repositioning the reference sensor part upstream from the working sensor parts, as opposed to downstream from the working sensor parts, would have been obvious to try. *Id.* at 16, 19 (citing Ex. 1024 ¶ 25).

With regard to limitation (*b*), Pharmatech argues that Schulman discloses taking multiple measurements in order to identify errors and that modifying Nankai to include this step would have been nothing more than the application of a known technique to improve a similar device with predictable results. *Id.* at 16-17, 21; Ex. 1024 ¶¶ 27-28. With regard to

limitation (c), Pharmatech argues that Schulman discloses giving an error indication if the difference parameter exceeds a predetermined threshold. Pet. 17 (citing Ex. 1007, 3:17-28; Ex. 1024 ¶¶ 27-28); *see also* Reply 3 (citing Ex. 1007, 21:32-36 (disclosing generating a signal only if sensor signals are within a prescribed amount of one another); *id.* at 22:20-23 (disclosing generating an error message if they are not within the prescribed amount)).

b. Patent Owner's Response

LifeScan presents several arguments in response to Pharmatech's challenge. We address them in turn.

(1) Position of Nankai's reference sensor part relative to working sensor parts

LifeScan argues that Nankai's test strip provides a reference sensor part downstream of the working sensor parts, rather than upstream as claimed. Resp. 17. This is not in dispute. *See* Pet. 11:2-3; *see also* section II.B.2.a, *supra* (Nankai Fig. 12 showing that reference electrode 5 is downstream of working electrodes 41, 42, 43).

(2) Criticality of positioning reference sensor part upstream

LifeScan argues that it would not have been obvious to reposition Nankai's reference sensor part to be upstream of the working sensor parts, because there is criticality in positioning the reference sensor part upstream. Resp. 17-18 (citing Ex. 2008 ¶ 43); Resp. 37 (citing Ex. 2008 ¶ 77). LifeScan argues that positioning the reference sensor part downstream of the working sensor parts, as Nankai does, would result in the reference sensor part being covered incompletely in the event an insufficient blood sample is

applied. *Id.* If the reference sensor part is covered incompletely, it will give an unreliable baseline potential, which would then cause measurements relative to the working sensor parts to be erroneous. *Id.* at 18. Nankai then would average those erroneous readings and not detect the error. *Id.* In contrast, if an inadequate sample is applied to a device in which the reference electrode is upstream, it will be instead one of the working electrodes that is covered incompletely. Ex. 2008 ¶ 38. That electrode will give a reading that differs significantly from the other working electrode. *Id*. If that difference exceeds the threshold, the error will be detected and an inaccurate measurement avoided. *Id.* LifeScan argues that Pharmatech's expert, Dr. Wang, does not address this criticality in his testimony. *Id.* at 50.

The criticality of a claimed feature may be demonstrated by showing that the specific feature claimed achieves unexpected results compared to the generic prior art. *In re Woodruff*, 919 F.2d 1575, 1578 (Fed. Cir. 1990) (addressing criticality of a claimed range within a broader prior-art range). Without such a showing, the advantage is no more than a new benefit of an old method, and cannot, by itself, render the method again patentable. *Id.*

LifeScan's argument is unpersuasive, because it does not explain how the advantage it identifies is an unexpected consequence of how the reference sensor part and the working sensor parts are positioned relative to one another. Whichever sensor part is furthest downstream is the one most likely to be covered incompletely when a sample of inadequate volume is applied. *See* Ex. 2008 ¶¶ 38, 43. LifeScan does not offer any credible evidence to suggest that it is unexpected that a downstream working sensor part, covered incompletely by the dregs of an inadequate sample, will report

a current measurement with a detectible discrepancy from the other, fully covered working sensor part.

(3) Disclosure in Nankai of multiple measurements

LifeScan argues that Nankai simply averages its multiple measurements, instead of comparing them to a difference parameter. Resp. 18-19 (citing Ex. 2008 ¶ 44); Resp. 37. LifeScan argues that Nankai's blind averaging would give inaccurate results if one of more of Nankai's working sensor parts were not completely filled with sample. *Id.* at 19.

This argument is unpersuasive, because Pharmatech relies on Schulman, not Nankai, for disclosing the comparison of multiple measurements to a difference parameter. *See* Pet. 16-17, 21. Pharmatech argues that it would have been obvious to apply this comparison technique to measurements made using Nankai's test strip. *Id.* How Nankai itself performs the comparison is irrelevant.

(4) Adequate sample size

LifeScan argues that Nankai fails to address the detection of an inadequately sized sample. Resp. 20-21 (citing Ex. 2008 ¶¶ 46-48). LifeScan argues that the '105 patent is directed to avoiding the incomplete coverage problem by minimizing sample size. *Id.* at 21 (citing Ex. 1002, 2:51-55). According to LifeScan, Nankai gives no consideration to this problem because it uses sample sizes so much larger than those disclosed in the '105 patent (five microliters or more, compared to two microliters or less), that samples were guaranteed to cover all the electrodes fully. *Id.* at 20-21. LifeScan acknowledges that the challenged claims do not place any limitations on the sample size, but argues that Nankai's failure to appreciate the problem of inadequate sample size is evidence that one of ordinary skill

in the art, attempting to solve the problem the '105 patent's inventors confronted, would not have considered Nankai. *Id.* at 21 (citing Ex. 2008 ¶ 48).

This argument is unpersuasive because, as LifeScan acknowledges, the claims do not limit the sample size, and LifeScan does not identify any other limitation in the claims to which the sample-size argument relates. Consequently, the claims encompass subject matter that this argument does not reach. *See In re Lintner*, 458 F.2d 1013, 1015 (CCPA 1972) ("Claims which are broad enough to read on obvious subject matter are unpatentable even though they also read on nonobvious subject matter."); *In re Muchmore*, 433 F.2d 824, 826 (CCPA 1970) (affirming obviousness rejection where claim "reads on both obvious and unobvious subject matter.").

This argument also is not persuasive because, when considering the rationale for combining references, "the problem examined is not the specific problem solved by the invention but the general problem that confronted the inventor before the invention was made." *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006). The rationale for combining references may be different from the inventor's specific reasons or goals for making the invention. *Id.* In the present case, the general problem confronting the inventors of the '105 patent was one of improving accuracy of the test strips. Ex. 1002, 1:15-18 ("the accuracy . . . is very important since an inaccurate reading could lead to the wrong level of insulin being administered which could be very harmful"). Pharmatech's rationale for combining Nankai and Schulman—that one of ordinary skill in the art would have recognized that Schulman's multisensor comparison method could improve the accuracy of

Nankai's multisensor test strip (Pet. 17)—addresses the same general problem.

(5) Whether Schulman discloses a disposable test strip

LifeScan argues that Schulman does not disclose a test strip having the claimed structure. Resp. 30. Specifically, LifeScan argues that Schulman does not disclose a test strip which has two working sensor parts and a common reference sensor part. *Id.* LifeScan also argues that Schulman does not disclose applying sample liquid to the test strip. *Id.* Specifically, LifeScan argues that Schulman's device is implanted in the body and is, therefore, in continuous contact with sample. *Id.* LifeScan describes Schulman's arrangement as "not related" to test strips that are used for intermittent measurements. *Id.* LifeScan also argues that Schulman uses the term "sensor" differently from how the term is used in the '105 patent. Resp. 28-29. According to LifeScan, the term "sensor," or more specifically, "sensor part," is used in the '105 patent to refer to a single electrode on a test strip, whereas a "sensor" in Schulman is an entire assembly of several electrodes and other structure. *Id.* at 29 (citing Ex. 1002, claims 1-3; Ex. 1007, 7:28-30; Ex. 2008 ¶ 59).

These arguments are unpersuasive, because Pharmatech does not rely on Schulman for any of these disclosures. Pharmatech relies on Schulman simply for the limited disclosure that multiple measurements of a sample can be made, compared to establish a difference parameter, and rejected if the difference exceeds a threshold. Pet. 16-17, 21; Reply 3; *see id.* at 6 ("the proposed [challenges] do not rely upon the specific sensor of Schulman"). That Schulman happens to disclose this technique in the context of

continuous monitoring by an implanted electrode, instead of intermittent monitoring by a disposable electrode, is of no moment.

LifeScan's arguments that (a) Schulman's measurement of oxygen depletion is not "in proportion" to the glucose concentration (Resp. 31-32, 37); (b) Schulman does not disclose a second sensor making an independent measurement (*id.* at 32-33); (c) Schulman does not compare the currents from its two sensors with one another directly because they measure different things (*id.* at 34, 37-38); and (d) Schulman does not disclose a single measuring device with multiple sensor parts (*id.* at 34-36, 38) each are unpersuasive for the same reason.

(6) "Fundamental technique" of measuring glucose.

LifeScan disputes our initial determination that Nankai, Schulman, and the '105 patent use the same "fundamental technique" for measuring glucose oxidase ("GOx")-mediated electrical current. Resp. 30-31 (citing Dec. 13). LifeScan argues that Schulman measures current resulting from oxygen reduction, not from a GOx-mediated oxidation of glucose followed by oxidation of a mediator. Resp. 31 (citing Ex. 2008 ¶ 68).

This argument is unpersuasive because LifeScan does not explain its relevance to the combinability of Nankai and Schulman. We also disagree with LifeScan's assertion. Schulman measures a GOx-mediated electrical current in the sense that the oxygen reduction it measures results from consumption of the oxygen by GOx to oxidize glucose in the blood. Ex. 1007, 3:35-62. We pointed out this similarity—the use of GOx and current measurements by each of Nankai, Schulman, and the '105 patent—to explain why we were not persuaded by LifeScan's Preliminary Response

argument that Schulman is non-analogous to single-use test strip technologies. Dec. 12-13 (citing Paper 10, 28).

(7) Combination of Nankai and Schulman

LifeScan argues that there is no evidence supporting a rationale to combine Nankai and Schulman and that, instead, the evidence shows that one of ordinary skill would have been led away from the combination. Resp. 38-43.

LifeScan argues that Schulman's glucose calculation method, which involves subtracting an oxygen depletion signal from a background oxygen signal to obtain a glucose result, is less accurate than the claimed method of comparing two glucose results. *Id.* at 40-41 (citing Ex. 2008 ¶ 83).

This argument is unpersuasive for the reason discussed above in subsection (5): Pharmatech relies on Schulman not for disclosure of the particular glucose measurement method, but rather only for disclosure of making multiple measurements and signaling an error if a difference parameter between the measurements exceeds a threshold. LifeScan does not credibly explain why it would not have been reasonable for one of ordinary skill in the art to have taken away from Schulman only this limited teaching. *See EWP Corp. v. Reliance Universal Inc*., 755 F.2d 898, 907 (Fed. Cir. 1985) ("A reference must be considered for everything it *teaches* by way of technology and is not limited to the particular *invention* it is describing and attempting to protect.").

LifeScan identifies other purported disadvantages of Schulman's glucose measurement method, including errors that would be introduced by the local generation of hydrogen peroxide and local deficit of oxygen. Resp. 41-42 (citing Ex. 2008 ¶¶ 84-85). These arguments are unpersuasive

for the same reason, because they depend on the incorporation of disclosure from Schulman beyond that which Pharmatech argues.

LifeScan argues that Schulman was less concerned with accuracy of individual measurements, because the continuous operation of the sensor would, instead, permit error detection by comparison of results over time. *Id.* at 42 (citing Ex. 2008 ¶ 88). Again, this argument is unpersuasive because it is not responsive to the challenge as Pharmatech has framed it.

LifeScan argues that Schulman's device has not been commercialized, and also that Dr. Smith never had any reason to consider implantable monitors in the course of decades of work seeking to improve disposable test strips. *Id.* at 43 (citing Ex. 2008 ¶¶ 86, 88-90). These arguments are unpersuasive, because they do not address why one of ordinary skill in the art would have been dissuaded from adapting the disclosure from Schulman that Pharmatech cites.

4. Objective evidence of nonobviousness

LifeScan argues that Pharmatech's copying of LifeScan's test strips demonstrates nonobviousness of claims 1-3. Resp. 45-49 (citing Ex. 2008 ¶¶ 92-95). LifeScan argues that Pharmatech's "GenStrip" test strip is similar to LifeScan's commercial strip. *Id.* at 46-48. LifeScan argues, and Pharmatech does not dispute in its Reply, that use of either a LifeScan test strip or a Pharmatech test strip with LifeScan's "One Touch Ultra" meter, to measure blood glucose, falls within the scope of claims 1-3. *Id*. at 47-48 (citing Ex. 2008 ¶¶ 92, 95). Pharmatech argues that its copying is not probative of obviousness because at least some level of copying was necessary to make its test strips operable with LifeScan's meter device, and because evidence of copying, without more, is not persuasive of

nonobviousness. Reply 14 (citing *Cable Elec. Products, Inc. v. Genmark, Inc.*, 770 F.2d 1015, 1028 (Fed. Cir. 1985), *overruled on other grounds by Midwest Indus., Inc. v. Karavan Trailers, Inc.*, 175 F.3d 1356, 1359 (Fed. Cir. 1999)).

5. Analysis

Nankai discloses a test strip having the structure recited in claim 1, expect for the position of the reference sensor part being upstream from the two working sensor parts. *Supra* at section II.B.2.a. Nankai's disclosure that the arrangement of its sensors may vary (Ex. 1003, 8:50-52) provides adequate reason for one of ordinary skill in the art to have repositioned the reference sensor part, in view of Dr. Wang's unrebutted[2] testimony (Ex. 1024 ¶ 25) that positioning the reference sensor part upstream of the working sensor parts was one of a finite number of possibilities and would have been obvious to try. *See KSR*, 550 U.S. at 417 (arrangement of prior-art elements that yields no more than expected results is obvious); *In re Kuhle*, 526 F.2d 553, 555 (CCPA 1975) (particular placement of electrical contact an obvious matter of design choice absent showing of an unexpected result). As discussed above in section II.B.3.b(2), we are unpersuaded that there is criticality in the positioning of the reference sensor, because LifeScan has not explained how any benefits flowing from the claimed position are unexpected.

The combination of Nankai with Schulman similarly is reasonable. Schulman's teachings about the need to compare independent concentration

[2] Dr. Smith acknowledges Dr. Wang's testimony but does not respond to it directly. S*ee* Ex. 2008 ¶ 42.

measurements, and signal an error if they diverge, transcend the particular sensor systems for which they are implemented. We agree with Pharmatech, and credit Dr. Wang's testimony, that one of ordinary skill in the art, seeking to improve the accuracy of a multisensor test strip such as Nankai's, would have had reason to use Schulman's comparison and error techniques. *See* Pet. 17; Ex. 1024 ¶ 27.

LifeScan's arguments to the contrary, discussed above in sections II.B.3.b(5)-(7), dwell on technical details of Schulman's sensor assemblies, not on the more general discussion of the need to detect divergence between redundant measurements in order to signal error. *See, e.g.*, Ex. 1007, 3:21-24 (calling for a "prescribed degree of correlation . . . to validate the correctness" of the measurement). LifeScan does not explain credibly why one of ordinary skill would have been deterred from using the general disclosure of Schulman by differences between Nankai's and Schulman's sensor structure or intended use.

Set against Pharmatech's evidence is LifeScan's evidence of copying by Pharmatech. LifeScan argues, and Pharmatech does not dispute, that measuring blood glucose with either company's test strip and LifeScan's meter falls within the scope of the claims. Resp. 47-48.

It is not sufficient, however, that a product or its use merely be within the scope of a claim in order for objective evidence of nonobviousness tied to that product or use to be given substantial weight. There must also be a causal relationship, termed a "nexus," between the evidence and the claimed subject matter. *Merck & Co., Inc. v. Teva Pharm. USA, Inc.*, 395 F.3d 1364, 1376 (Fed. Cir. 2005). A nexus is required in order to establish that the evidence relied upon traces its basis to the claimed subject matter, not to

another source. *Institut Pasteur & Universite Pierre Et Marie Curie v. Focarino*, 738 F.3d 1337, 1347 (Fed. Cir. 2013). The stronger the showing of nexus, the greater the weight accorded the objective evidence of nonobviousness. *See Ashland Oil, Inc. v. Delta Resins & Refractories, Inc.*, 776 F.2d 281, 306 (Fed. Cir. 1985), *cert. denied*, 475 U.S. 1017 (1986). Like other types of objective evidence, evidence of copying must be shown to have nexus. *Wm. Wrigley Jr. Co. v. Cadbury Adams USA LLC*, 683 F.3d 1356, 1364 (Fed. Cir. 2012). A showing of nexus is required in order to demonstrate that the claimed subject matter drove the copying. *See Institut Pasteur*, 738 F.3d at 1338; *see also Cable Elec. Products*, 770 F.2d. at 1028 (copying could result from lack of concern about patent property, contempt for the patent, or accepted practices in the industry, among others).

LifeScan does not direct any argument or credible evidence to the issue of nexus. Instead, LifeScan argues, and Pharmatech does not dispute, that the copying was motivated by a desire to make Pharmatech's test strips compatible with LifeScan's "One Touch Ultra" meter system. Resp. 47 (citing Ex. 2008 ¶ 43); Reply 14 (acknowledging that "some level of copying was necessary to get the GenStrip to work with Lifescan OneTouch Ultra meters"). LifeScan does not show or explain credibly how this reason for copying relates to the claimed subject matter, as opposed to unclaimed features, or to considerations unrelated to the invention.

Pharmatech makes a rational argument for obviousness of claims 1-3 over Nankai and Schulman. As discussed above, we agree with Pharmatech that the evidence of record establishes that it would have been a matter of design choice to reposition Nankai's reference sensor to be upstream of the working sensor parts, and that one of ordinary skill would have had reason

to adapt Schulman's comparison and error-signaling methods to Nankai's system.

LifeScan's objective evidence of copying is not sufficient to overcome Pharmatech's obviousness argument. As noted above, evidence of copying requires a nexus with the claimed subject matter. But LifeScan's evidence has not been tied credibly to the claims under review. As a result, the causal relationship between the claimed subject matter and the objective evidence is tenuous.

Because LifeScan has not shown nexus convincingly, the objective evidence does not persuade us that the apparent copying of its test strips can be traced to the claimed subject matter. When we balance Pharmatech's evidence of obviousness against the objective evidence of nonobviousness, we determine that a preponderance of the evidence supports Pharmatech's argument that it would have been obvious to combine Nankai and Schulman to reach the subject matter of claims 1-3.

Accordingly, we conclude that Pharmatech has demonstrated the unpatentability of claims 1-3 for obviousness over Nankai and Schulman, by a preponderance of the evidence.

C. Obviousness over Winarta and Schulman

Pharmatech argues that claims 1-3 are unpatentable under 35 U.S.C. § 103(a) over Winarta in combination with Schulman. Pet. 42-46. LifeScan responds, both arguing that Pharmatech has not demonstrated the obviousness of the claims (Resp. 21-43), and presenting objective evidence of nonobviousness. Resp. 45-49.

Again, we undertake the four factual inquiries of an obviousness analysis.

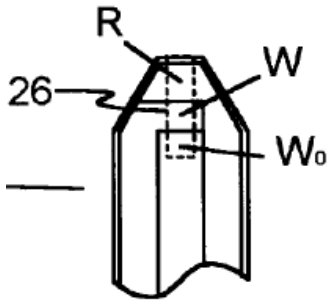
1. The level of skill in the art

The discussion presented above in section II.B.1 is equally applicable here.

2. Scope and content of the prior art

a. Overview of Winarta

Winarta describes a disposable GOx-coated electrode test strip used to calculate glucose in a blood sample by measuring current. Ex. 1005, 7:11-42. Detail from Figure 2 of Winarta is reproduced below:



The detail from Figure 2 shows the tip of a test strip. Reference electrode R, working electrode W, and pseudo-working electrode W_0 are positioned in electrode area 26. *Id.* at 8:63-67. All three electrodes are coated with a reagent mix that includes GOx. *Id.* at 7:25-26, 28, 41-42. A fluid channel runs over the electrodes, and the electrodes are arranged in the order R–W–W_0 from the open end, so that fluid entering the strip flows first over R, then W, and then W_0. *Id.* at 5:59-62. Flow onto W_0 causes a current that triggers a meter to begin a measurement. *Id.* at 5:64-65. W_0 also may be used as a counter electrode, and measurements may be taken between R and W_0. *Id.* at 6:1-10.

b. Schulman

The overview of Schulman presented above in section II.B.2.b is equally applicable here.

3. Differences between the claimed subject matter and the prior art

a. Petitioner's Case-in-Chief

Pharmatech argues that Winarta discloses all limitations of claim 1 except (*a*) measuring an electric current at a *second* working sensor part; (*b*) comparing the electric current from each of the working sensor parts to establish a difference parameter; and (*c*) giving an indication of an error if the difference parameter is greater than a predetermined threshold. Pet. 42-46. Pharmatech argues that Schulman discloses all three missing limitations. *Id.* at 43, 45-46. With particular reference to the claim requirement that the first and second working sensor generate "substantially identical" quantities of charge carriers in the absence of an error condition, Pharmatech argues that Winarta Figure 2 shows that W and W_0 are the same size, but that, even if they are not, it would have been obvious to make them the same size in order to take advantage of Schulman's comparisons based on multiple measurements. *Id.* at 44-45 (citing Ex. 1024 ¶ 61).

With regard to limitation (*a*), Pharmatech argues that, because Winarta describes W_0 as capable of being used to take measurements, it would have been obvious to modify Winarta to do so in view of Schulman's disclosure to use two or more sensors to confirm reliability of a measurement. *Id.* at 43, 45 (citing Wang Decl. ¶ 63). With regard to limitations (*b*) and (*c*), Pharmatech argues, as it did in the Nankai/Schulman challenge, that modifying Winarta to include these steps would have been

nothing more than the application of a known technique to improve a similar device with predictable results. *Id.*

b. Patent Owner's Response

LifeScan presents several arguments in response to Pharmatech's challenge. We address them in turn.

(1) Uses of W_0

LifeScan argues that electrode W_0 is not disclosed by Winarta as being a working sensor part. Resp. 21-22. LifeScan argues W_0 is incapable of making a glucose measurement, because none of the roles for W_0 disclosed in Winarta—as counter electrode, resistance sensor, or trigger—can be used to make such a measurement. *Id.* at 22-25 (citing Ex. 2008 ¶¶ 18, 53-55).

This argument is unpersuasive, because Pharmatech's challenge is not premised on operating W_0 in the role of a counter electrode, resistance sensor, or trigger in order to obtain a glucose measurement. LifeScan presents numerous technical explanations as to why, for example, an electrode serving as a counter electrode could not be used to measure glucose, but none of those explanations is germane to the challenge that Pharmatech has presented. Pharmatech argues that the structural features of W_0 (such as its reagent coating), and its arrangement with the other parts of Winarta's test strip, make it capable of being operated in an additional manner: as a working electrode. Pet. 42-44. In this mode, W_0 could be used to make a second glucose measurement, in addition to the measurement made at W.

Pharmatech has presented a reasonable explanation, supported by expert testimony, that W_0 is capable of being used as a working electrode.

In particular, Pharmatech has shown that W_0 is formed as an electrode and is coated with the same reagents as W. *See* Pet. 42-44; Ex. 1024 ¶ 49. We are persuaded that W_0 is capable of being operated as a working electrode. LifeScan has not explained what essential structural feature W_0 lacks, or what extraneous structural feature it possesses, that would render W_0 incapable of functioning as a working electrode. LifeScan has not credibly explained why Pharmatech's argument on this point is in error.

(2) External circuit arrangement in Winarta

LifeScan argues that Winarta does not disclose any external circuit arrangement or calculation method in a device to allow glucose measurement at W_0. Resp. 25 (citing Ex. 2008 ¶ 55).

This argument is unpersuasive, because Winarta does have circuitry for making measurements involving W_0. *See* Ex. 1005, 6:5-7 (W_0 can be used with R to measure sample resistance). Upon consideration of the record, we are persuaded that the modifications required to the existing external circuitry would have been within the ability of one of ordinary skill in the art.

(3) Modification of W_0 to make glucose measurements

LifeScan argues that, because Winarta already discloses three uses for W_0, there would have been no reason for one of ordinary skill to employ it for the undisclosed use of making a glucose measurement. Resp. 25 (citing Ex. 2008 ¶ 55). This argument is not persuasive, because LifeScan does not explain why three disclosed uses would have prevented or dissuaded one of ordinary skill from considering a fourth use.

(4) Size of W_0

LifeScan argues that, even if there were reason to use W_0 as a second working electrode, it would need to be of equal size to W, in order to meet the claim limitation that the two working sensor parts generate substantially identical quantities of charge carriers. Resp. 25-26. LifeScan argues that Winarta is silent as to whether W_0 is the same size as W. *Id.* at 26 (citing Ex. 2008 ¶ 54). As noted above, Pharmatech argues that Figure 2 of Winarta shows that W and W_0 have the same size and that, even if they were not uniform in size, it would have been obvious to make them so, in order to employ Schulman's methods for comparing multiple measurements. Pet. 44-45 (citing Ex. 1024 ¶ 61).

We agree with LifeScan that Winarta is silent as to whether W and W_0 are of the same size. Pharmatech relies on a patent drawing, and on an expert's interpretation of that patent drawing. *See* Pet. 44; Ex. 1024 ¶ 61. But unless a patent drawing is indicated as being to scale, it generally is not to be relied upon for precise proportions. *In re Wright*, 569 F.2d 1124, 1127 (CCPA 1977). There are, then, three possibilities for the size of W_0 relative to W: smaller, equal, or larger. We credit Dr. Wang's testimony that it would have been obvious to make them the same size in the course of adapting Schulman's comparison method to Winarta's test strip. *See* Ex. 1024 ¶ 61.

(5) Whether the combination of Winarta and Schulman meets all limitations

LifeScan argues that the combination of Winarta and Schulman fails to meet all limitations of the challenged claims. Resp. 44-45. LifeScan points out that Winarta does not disclose a test strip with two working sensor

parts, and that Schulman does not remedy this deficiency. *Id.* at 44 (citing Ex. 2008 ¶¶ 50-55). LifeScan also argues that, because of this deficiency, neither Winarta nor Schulman discloses comparing the electric current from two working sensor parts. *Id.* at 44-45 (citing Ex. 2008 ¶ 81).

These arguments are unpersuasive, because they address the references individually. The relevant inquiry is what the combination of the references would have conveyed to one of ordinary skill in the art. Pharmatech argues that Schulman's comparison method would have led one of ordinary skill to make Winarta's W_0 electrode the same size as W and to use it as a second working sensor part. Pet. 44-45. Under Pharmatech's argument, the notion of a test strip with two working sensor parts would have emerged from the combination of Winarta and Schulman, not from either reference by itself. *See EWP*, 755 F.2d at 907 ("On the issue of obviousness, the combined teachings of the prior art as a whole must be considered.").

(6) Whether one of ordinary skill would have been led to combine Winarta and Schulman

LifeScan asserts that the arguments it gave concerning the combination of Nankai and Schulman, discussed above in section II.B.3.b(7), are applicable to the combination of Winarta and Schulman. Resp. 45. These arguments are not persuasive, for the reasons given in that section.

4. Objective evidence of nonobviousness

The discussion presented above in section II.B.4 is equally applicable here.

5. Analysis

Winarta discloses a test strip having the structure recited in claim 1, except for specifying that one of the electrodes, W_0, is a working sensor part and would generate a number of charge carriers substantially identical to the number of charge carriers generated by the other working sensor part. As discussed above in section II.C.3.b(1), we agree with Pharmatech that W_0 has the structural features necessary to function as a working sensor part.

The combination of Winarta with Schulman is reasonable, for the reasons discussed above. We credit Dr. Wang's testimony that one of ordinary skill in the art would have had reason to implement Schulman's multiple measurement and comparison method in Winarta's device and would have thought to adapt W_0 as a second working electrode during that implementation. *See* Ex. 1024 ¶¶ 63-64. LifeScan's technical critique of Schulman's sensor assemblies does not persuade us that one of ordinary skill in the art would not have adapted other disclosure from Schulman for use in Winarta. LifeScan's evidence of copying is entitled to little weight, because LifeScan has not shown a nexus between that evidence and the claims, as discussed above in section II.B.5. When we balance Pharmatech's evidence of obviousness against the objective evidence of nonobviousness, we determine that a preponderance of the evidence supports Pharmatech's argument that it would have been obvious to combine Winarta and Schulman to reach the subject matter of claims 1-3.

Accordingly, we conclude that Pharmatech has demonstrated the unpatentability of claims 1-3 for obviousness over Winarta and Schulman, by a preponderance of the evidence.

III. CONCLUSION

Pharmatech has proved, by a preponderance of the evidence, that the subject matter of claims 1-3 would have been obvious over the combined teachings of Nankai and Schulman, as well as over the combined teachings of Winarta and Schulman.

IV. ORDER

For the reasons given, it is

ORDERED that claims 1-3 of U.S. Patent No. 7,250,105 B1 are determined to be UNPATENTABLE; and

FURTHER ORDERED that because this is a final decision, parties to the proceeding seeking judicial review of the decision must comply with the notice and service requirements of 37 C.F.R. § 90.2.

FOR PETITIONER:

William A. Rudy
A. Justin Poplin
LATHROP & GAGE LLP

FOR PATENT OWNER:

Dianne B. Elderkin
Steven Maslowski
AKIN GUMP STRAUSS HAUER
& FELD LLP

EXHIBIT 1002:

U.S. PAT. NO. 7,250,105 TO DAVIES. ("THE '105 PATENT")

(12) **United States Patent**
Davies et al.

(10) **Patent No.: US 7,250,105 B1**
(45) **Date of Patent: *Jul. 31, 2007**

(54) **MEASUREMENT OF SUBSTANCES IN LIQUIDS**

(75) Inventors: **Oliver W. H. Davies**, Inverness (GB); **Christopher P. Leach**, Inverness (GB); **Manuel Alvarez-Icaza**, Inverness (GB)

(73) Assignee: **Lifescan Scotland Limited**, Scotland (GB)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 369 days.

This patent is subject to a terminal disclaimer.

(21) Appl. No.: **10/431,140**

(22) Filed: **May 7, 2003**

Related U.S. Application Data

(63) Continuation of application No. 09/521,163, filed on Mar. 8, 2000, now Pat. No. 6,733,655.

(51) **Int. Cl.**
G01N 27/327 (2006.01)
G01N 27/333 (2006.01)

(52) **U.S. Cl.** **205/777.5**; 205/789

(58) **Field of Classification Search** 204/403.01–403.14, 416–418; 205/777.5, 205/778, 792
See application file for complete search history.

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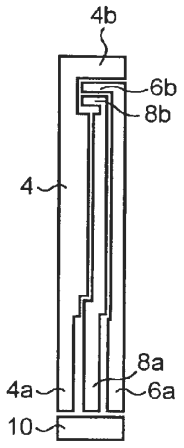
Primary Examiner—Alex Noguerola

(57) **ABSTRACT**

In accordance with the present invention a measuring device compares the current generated by two working sensor parts and gives an error indication if they are too dissimilar, i.e., the current at one sensor part differs too greatly from what would be expected from considering the current at the other. Not only can this method detect when one of the sensor parts has not been properly covered with sample liquid, but it can also detect if there is a manufacturing defect in either sensor part or if either has been damaged after manufacture, since even with complete coverage of the working sensor parts, an anomalous current will be generated at the affected sensor part under such circumstances.

3 Claims, 2 Drawing Sheets



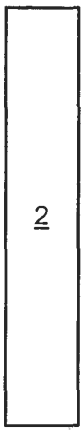


FIG. 1

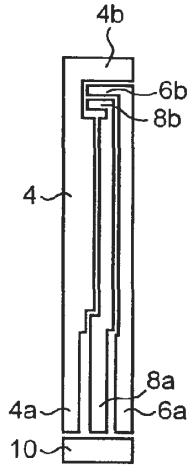


FIG. 2

FIG. 3

FIG. 4

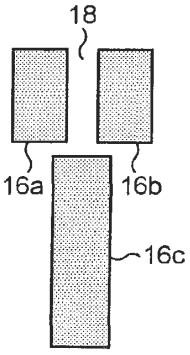


FIG. 5

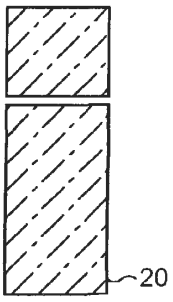


FIG. 6

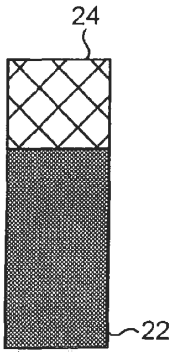


FIG. 7

Pharmatech Solutions, Inc: 1002-2
REQUEST FOR INTER PARTES REVIEW
OF U.S. PATENT NUMBER 7,250,105

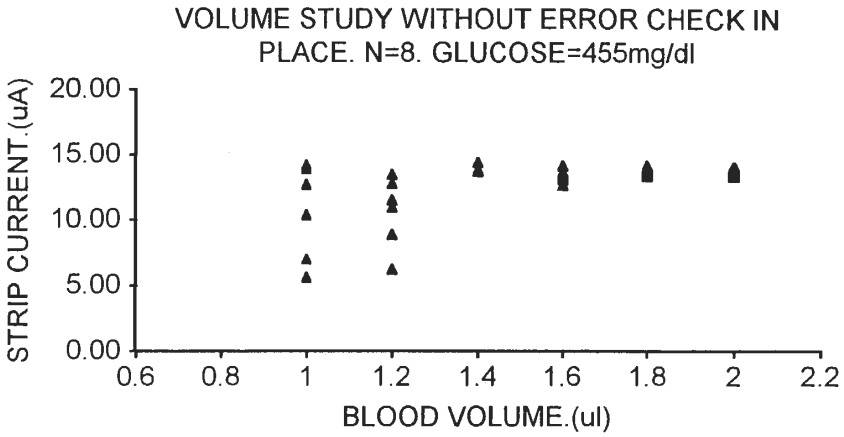

VOLUME STUDY WITHOUT ERROR CHECK IN PLACE. N=8. GLUCOSE=455mg/dl
STRIP CURRENT.(uA)
20.00
15.00
10.00
5.00
0.00
0.6
0.8
1
1.2
1.4
1.6
1.8
2
2.2
BLOOD VOLUME.(ul)

FIG. 8

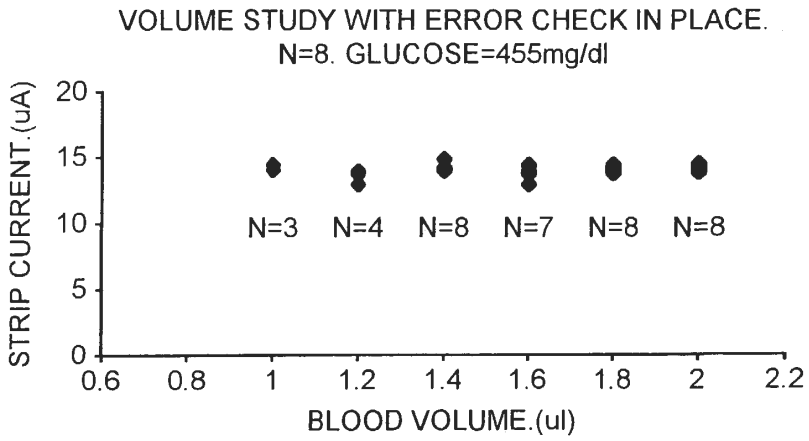

VOLUME STUDY WITH ERROR CHECK IN PLACE. N=8. GLUCOSE=455mg/dl
STRIP CURRENT.(uA)
20
15
10
5
0
N=3
N=4
N=8
N=7
N=8
N=8
0.6
0.8
1
1.2
1.4
1.6
1.8
2
2.2
BLOOD VOLUME.(ul)

FIG. 9

MEASUREMENT OF SUBSTANCES IN LIQUIDS

This application is a Continuation application of Ser. No. 09/521,163 filed Mar. 8, 2000, now U.S. Pat. No. 6,733,655, which is incorporated herein by reference in its entirety.

This invention relates to apparatus for measuring the concentration of a substance in a liquid and particularly, but not exclusively, to apparatus for measuring the concentration of glucose in blood.

Devices for measuring blood glucose levels are invaluable for diabetics, especially devices that may be used by the sufferers themselves since they may then monitor their own glucose levels and take an appropriate dose of insulin. Correspondingly therefore the accuracy of such devices is very important since an inaccurate reading could lead to the wrong level of insulin being administered which could be very harmful.

lt is also the case that in all practical blood glucose measuring systems at least part of the device, i.e. that part which comes into contact with the sample blood, is disposable. This means that it is particularly important that the cost particularly of any disposable parts can be minimised as a user will generally need large numbers of them regularly.

Known glucose measuring devices now favour an electrochemical measurement method over old colorimetric methods. The general principle is that an electric current is measured between two sensor parts called the working and reference sensor parts respectively. The working sensor part comprises a layer of enzyme reagent, the current being generated by the transfer of electrons from the enzyme substrate, via the enzyme and an electron mediator compound to the surface of a conductive electrode. The current generated is proportional to both the area of the sensor part and also the concentration of glucose in the test sample. Since the area of the working sensor part is supposedly known, the electric current should be proportional to the glucose concentration.

lt has been recognised in the art that inaccurate results are obtained if the working sensor part is not fully covered with blood since then its effective area is reduced. Various ways of dealing with this problem have been proposed, two of which are disclosed in U.S. Pat. No. 5,628,890 and U.S. Pat. No. 5,582,697 Both of these methods rely on a unidirectional flow of blood across the surface of the test strip and both initiate the test measurement by detecting the presence of the sample liquid at an electrode or sensor part located downstream of the working sensor part.

The problem of insufficient sample liquid being present and thus the working sensor part not being completely covered may of course be reduced by reducing the size of the working sensor part. However a small area for the working sensor part tends to give a greater variability in calibrated results.

The present inventors have realised that as well as incomplete coverage of the working sensor part, inaccurate results can also arise from occasional defects in the production of the test strips for such devices, in the area and/or the thickness of the working sensor part and also from accidental damage to the working sensor part e.g by a user. As far as the inventors are aware, the only practical way to deal with this problem so far has been to ensure that the printing process used to produce the test strips is as accurate as possible and to rely on adequate quality control.

lt is an object of the present invention at least partially to alleviate the above-mentioned disadvantages and when viewed from a first aspect the invention provides a method

of measuring the concentration of a substance in a sample liquid comprising the steps of:

providing a measuring device having a first working sensor part comprising a working layer which generates an electric current proportional to the concentration of said substance in the sample liquid, a reference sensor part and a second working sensor part comprising a working layer which also generates an electric current proportional to the concentration of said substance in the sample liquid;

applying the sample liquid to said measuring device;

comparing the electric current generated at each of the working sensor parts to establish a difference parameter; and

giving an indication of an error if said difference, parameter is greater than a predetermined threshold.

Furthermore the measuring device used in this method is novel and inventive in its own right and thus from a second aspect the present invention provides a device for measuring the concentration of a substance in a sample liquid, said device comprising:

a reference sensor part,

a first working sensor part, comprising a working layer for generating an electric current proportional to the concentration of said substance in the sample liquid; and

a second working sensor part comprising a working layer also for generating an electric current proportional to the concentration of said substance in the sample liquid.

Thus it will be seen that in accordance with the invention the measuring device compares the current generated by two working sensor parts and gives an error indication if they are too dissimilar—i.e. the current at one sensor part differs too greatly from what would be expected from considering the current at the other. Not only can this method detect when one of the sensor parts has not been properly covered with sample liquid, but it can also detect if there is a manufacturing defect in either sensor part or if either has been damaged after manufacture, since even with complete coverage of the working sensor parts, an anomalous current will be generated at the affected sensor part such circumstances.

ln accordance with the invention the only type of defect or damage which would not necessarily be recognised is one which affected both of the working sensor parts to the same degree. However, this is logically less likely than a defect affecting a single working sensor part and is thus an improvement over the prior art. ln practice such a likelihood is considered to be negligible. ln any event the invention is not limited to providing just two working sensor parts and the skilled person could therefore choose to provide three or more working sensor parts to further reduce the probability that they are all affected by an identical defect.

Looking at the invention another way, it provides an arrangement whereby for a given total area of working sensor part and thus a given minimum sample volume, detection of inadequate fill and of defects in the working sensor part provided by separating the area of the working sensor part into two.

Some or all of the sensor parts may be provided as part of an integrated device. Preferably however at least the working sensor parts are provided on a removable test member. Thus when viewed from a further aspect the present invention provides a test member for measuring the concentration of a substance in a sample liquid comprising:

a substrate; and

two working sensor parts provided on the substrate, each working sensor part comprising a working layer for generating an electric current proportional to the concentration of said substance in the sample liquid.

Preferably a reference sensor part is also provided on the substrate.

It will be appreciated by those skilled in the art that effectively what has been provided is a measuring device which is self-testing for proper use, damage and certain manufacturing defects. This is particularly beneficial in the context of a device in which the sensor parts are provided on a separate test member since this may typically be a mass-manufactured test strip, e.g. for measuring blood glucose levels. Since in accordance with the invention a damaged or defective test strip will be recognised, allowing it to be rejected, the accuracy of the final result and thus potentially the safety of a user is no longer solely dependent upon high manufacturing precision. Although it is of course not desirable that a large number of tests is rejected, in many circumstances it is more important that inaccurate results are not given.

The two working sensor parts may be dissimilar or different potentials may be applied to each sensor part in either of which cases the measuring device is preferably arranged to apply appropriate weights to the measurements returned by one or both working sensor parts to normalise them. The difference parameter could then for example be the simple arithmetic difference between the normalised current values. Preferably however the working layer of both sensor parts is of the same material and alternatively, but preferably additionally, both working sensor parts have the same area. Thus it is most preferred that the two working sensor parts are substantially identical. It is also preferred that the measuring device is arranged to apply the same potential to each sensor part. This allows the difference parameter to comprise a direct comparison between the respective currents at the sensor parts in order to determine whether a reliable measurement of the substance concentration can be made.

The two working sensor parts may be arranged as convenient within the device, or in accordance with the preferred embodiment, on the test member. The device or test member may be arranged to allow the sample liquid to flow freely over the working sensor parts. More preferably however the sample liquid is constrained to flow substantially unidirectionally across the working sensor parts.

It is presently preferred that the two working sensor parts are arranged one downstream of the other. This makes it possible to ensure that one of the sensor parts will always be completely covered before the other begins to be covered, thus avoiding the possibility, however small, that insufficient sample liquid is applied to cover both sensor parts and furthermore that each sensor part is partially covered by the same amount. It will be appreciated however that if the above-mentioned small risk is deemed acceptable, arrangements in accordance with the invention allow a much greater flexibility in the placement of the sensor parts than in known devices whilst still providing protection against an inadequate volume of sample liquid being used or other incorrect product usage or damage. It is also preferred that both working sensor parts are downstream of the reference sensor part.

The threshold used to determine an inaccurate measurement may be chosen as appropriate. Typically a threshold will be chosen empirically as a suitable value will depend on the inherent variability in the manufacturing process, the desired precision of results, etc. To some extent there is a trade-off between the accuracy which may be obtained by setting the threshold low and the proportion of measurements which are disregarded as being too inaccurate. Thus the threshold might advantageously be set at a level for example where no significant harm would be done to a patient relying on the results to administer insulin.

The difference parameter may be an absolute value—e.g. of the difference in currents measured at each sensor part, but is preferably dimensionless—e.g. a percentage of one or other of the measured currents.

The actual current value used to calculate the concentration of the substance may just be that from one of the working sensor parts, but is preferably a combination thereof, e.g. the sum or mean of the two. This gives the advantage that the maximum effective working area is utilised which further helps to increase the precision of the results obtained.

A particularly preferred embodiment of the invention is a device for measuring the concentration of glucose in blood, in which the two working sensor parts and the reference sensor part are provided on a disposable test strip.

A preferred embodiment of the invention will now be described, by way of example only, with reference to the accompanying drawings in which:

FIG. **1** shows a substrate for a test strip in accordance with the invention;

FIG. **2** shows the layout of carbon tracks applied to the substrate;

FIG. **3** shows the layer of insulation applied to the strip;

FIG. **4** shows the enzyme reagent layer;

FIG. **5** shows a layer of hydrophilic film;

FIG. **6** shows the cover layer of the strip;

FIG. **7** is a plot of the results obtained without using a method in accordance with the invention; and

FIG. **8** is a plot similar to FIG. **7** obtained using a method in accordance with the invention.

FIG. **9** is a plot similar to FIG. **8** obtained using a method in accordance with the invention.

Turning to FIG. **1**, there is shown an oblong polyester strip **2** which forms the substrate for a test strip for measuring the concentration of glucose in a sample of blood. The substrate **2** is shown in isolation although in practice an array of such strips is cut out from a large master sheet at the end of fabrication.

FIG. **2** shows the pattern of carbon ink which is applied to the substrate by screen printing. The layer of carbon comprises four distinct areas which are electrically insulated from one another. The first track **4** forms, at the distal end thereof, an electrode **4***b* for a reference/counter sensor part. The track **4** extends lengthwise to form a connecting terminal **4***a* at its proximal end. The second and third tracks **6**, **8** form electrodes **6***b*, **8***b* at their distal ends for two working sensor parts and respective connecting terminals **6***a*, **8***a* at their proximal ends. The fourth carbon area is simply a connecting bridge **10** which is provided in order to close a circuit in a suitable measuring device in order to turn it on when the test strip has been properly inserted.

FIG. **3** shows the next layer to be applied also by screen printing. This is a water insoluble insulating mask **12** which defines a window over the electrodes **6***b*, **8***b* and which therefore controls the size of the exposed carbon and hence where the enzyme layer **14** (FIG. **4**) will come into contact with the carbon electrodes. The size and shape of the window are set so that the two electrodes **6***b*, **8***b* have a patch of enzyme of exactly the same area printed onto them. This means that for a given potential, each working sensor part will theoretically generate the same electric current in the presence of a sample of blood.

A layer of glucose oxidase **14** (FIG. **4**) is printed over the mask **12** and thus onto the electrodes **4***b*, **6***b*, **8***b* through the window in the mask to form the reference/counter sensor

part and the two working sensor parts respectively. A 150 micron layer of adhesive is then printed onto the strip in the pattern shown in FIG. **5**. This pattern has been enlarged for clarity as compared to the previous Figures. Three separate areas of adhesive **16***a, b, c* together define a sample chamber **18** between them.

Two sections of hydrophilic film **20** (FIG. **6**) are laminated onto the strip and are held in place by the adhesive **16**. The first section of film has the effect of making the sample chamber **18** into a thin channel which draws liquid into and along it by a capillary action. The final layer is shown in FIG. **7** and is a protective plastic cover tape **22** which has a transparent portion **24** at the distal end. This enables a user to tell instantly if a strip has been used.

Use of the strip will now be described. The test strip is inserted into the meter. The bridge portion **10** completes a circuit in the device and thus automatically turns the device on. The device also has contacts to connect to the terminals **4***a*, **6***a*, **8***a* on the strip. The measuring device applies a potential of 400 mV between the counter/reference sensor part and each of the two working sensor parts via the above-mentioned terminals.

A drop of blood is then placed on the distal end of the strip. Capillary action draws the blood along the sample chamber **18** and over the counter/reference sensor part and two working sensor parts.

After a predetermined time the electric current generated by each working sensor part is measured and the two measurements are compared. If they differ by more than 10% an error message is displayed on the measuring device and the test must be repeated. If they are within 10% of each other however, the two currents are added together in the device and are converted to a glucose level which is displayed on an LCD.

A comparative experiment was carried out using a strip fabricated as set out above, in order to exemplify the benefits achievable in accordance with the invention. In the experiment drops of blood increasing in volume from 1 to 2 micro liters in steps of 0.2 micro liters and with a constant glucose concentration, were applied to such strips, with each volume being repeated 8 times. The current measured at each working sensor part was measured and recorded. The results are shown in Table 1 appended to this description.

For the first part of the test the two currents were simply added together to simulate a single working sensor part having their combined area. These results are plotted in FIG. **8**.

In the second half of the test the two currents were first compared. Only if they differed by less than 10% were they then added together and put forward as valid results. Values differing by more than 10% were disregarded. The results of this second part of the test are plotted in FIG. **9**.

It is immediately apparent that the second set of results is significantly more precise, i.e. they display a much lower variation. Furthermore, since in practice the two working sensor parts will only give results consistent with one another if they are both fully covered, the second set of results is also significantly more accurate than the first since it may be safely assumed that the results are only actually given when both working sensor parts are fully covered.

Thus is will-be seen that in its preferred embodiment the present invention allows the detection and rejection of those tests that have had insufficient sample applied to the test strip i.e those in which the test strip has been incorrectly used.

It will be appreciated by those skilled in the art that many variations on what has been described above are possible within the scope of the invention. For example the invention may be used to measure the level of any suitable substance in any liquid, not just glucose in blood. Furthermore, the working sensor parts need not be provided on a test strip but may be part of an integrated device. Also the difference figure of 10% used in the embodiment described above is purely exemplary and any suitable figure may be chosen.

TABLE 1

Volume µL	Working 1: µA	Working 2: µA	% Difference	Error checked	No error check
1	7.07	0.00	−706800		7.07
1	6.94	5.98	−16.2175732		12.92
1	5.53	0.01	−92050		5.54
1	6.99	7.09	1.42393909	14.09	14.09
1	7.34	7.02	−4.59016393	14.35	14.35
1	7.16	6.79	−5.49742078	13.94	13.94
1	7.01	3.47	−102.13441		10.48
1	7.07	5.69	−24.2578605		12.77
1.2	7.18	4.54	−58.2286847		11.72
1.2	7.00	6.78	−3.35055351	13.78	13.78
1.2	7.09	1.79	−297.032475		8.88
1.2	6.31	0.00	−157550		6.31
1.2	6.78	6.79	0.11788977	13.56	13.56
1.2	6.95	6.59	−5.4029443	13.53	13.53
1.2	6.62	6.28	−5.36795158	12.89	12.89
1.2	7.23	3.78	−91.2721502		11.01
1.4	7.16	6.90	−3.76811594	14.06	14.06
1.4	7.14	6.94	−2.88184438	14.08	14.08
1.4	7.17	7.02	−2.13675214	14.19	14.19
1.4	7.02	6.01	−1.5918958	13.93	13.93
1.4	6.95	6.91	−0.5788712	13.86	13.86
1.4	6.93	6.88	−0.72674419	13.81	13.81
1.4	7.09	6.92	−2.4566474	14.01	14.01
1.4	7.25	7.40	2.02702703	14.65	14.65
1.6	7.808	6.59	−18.4825493		14.40
1.6	6.774	6.589	−2.80770982	13.36	13.36
1.6	6.928	6.904	−0.34762457	13.83	13.83
1.6	6.892	6.453	−6.80303735	13.35	13.35
1.6	7.087	7.314	3.10363686	14.40	14.40
1.6	7.257	6.947	−4.46235785	14.20	14.20
1.6	6.501	6.306	−3.09229305	12.81	12.81
1.6	6.811	6.755	−0.82901554	13.57	13.57
1.8	7.145	6.536	−9.31762546	13.68	13.68
1.8	7.021	6.612	−6.18572293	13.63	13.63
1.8	6.917	6.828	−1.30345636	13.75	13.75
1.8	6.971	6.78	−2.81710914	13.75	13.75
1.8	7.016	6.941	−1.08053595	13.96	13.96
1.8	6.977	7.179	2.81376236	14.16	14.16
1.8	6.946	6.794	−2.23726828	13.74	13.74
1.8	7.203	7.183	−0.27843519	14.39	14.39
2	7.145	6.536	−9.31762546	13.68	13.68
2	7.021	6.621	−6.18572293	13.63	13.63
2	6.917	6.828	−1.30345636	13.75	13.75
2	6.971	6.78	−2.81710914	13.75	13.75
2	7.016	6.941	−1.08053595	13.96	13.96
2	6.977	7.179	2.81376236	14.16	14.16
2	6.946	6.794	−2.23726818	13.74	13.74
2	7.203	7.183	−0.27843519	14.39	14.39

The invention claimed is:

1. A method of measuring the concentration of a substance in a sample liquid comprising the steps of:

providing a measuring device said device comprising:

a first working sensor part for generating charge carriers in proportion to the concentration of said substance in the sample liquid;

a second working sensor part downstream from said first working sensor part also for generating charge carriers in proportion to the concentration of said substance in the sample liquid wherein said first and second working sensor parts are arranged such that, in the absence of an error condition, the quantity of said charge carriers generated by said first working sensors part are substantially identical to the quantity of said charge carriers generated by said second working sensor part; and

a reference sensor part upstream from said first and second working sensor parts which reference sensor part is a common reference for both the first and second working sensor parts, said reference sensor part and said first and second working sensor parts being arranged such that the sample liquid is constrained to flow substantially unidirectionally across said reference sensor part and said first and second working sensor parts; wherein said first and second working sensor parts and said reference sensor part are provided on a disposable test strip;

applying the sample liquid to said measuring device;

measuring an electric current at each working sensor part proportional to the concentration of said substance in the sample liquid;

comparing the electric current from each of the working sensor parts to establish a difference parameter; and

giving an indication of an error if said difference parameter is greater than a predetermined threshold.

2. The method as claimed in claim **1** comprising measuring the current at each working sensor part after a predetermined time following application of the sample.

3. The method as claimed in claim **1** wherein the substance to be measured is glucose, and each of the working sensor parts generates charge carriers in proportion to the concentration of glucose in the sample liquid.

* * * * *

CERTIFICATE OF COMPLIANCE

Pursuant to Federal Rule of Appellate Procedure 32(a)(7)(C) and Federal Circuit Rule 32(b), the undersigned hereby certifies that this brief complies with the type-volume limitation of Federal Rule of Appellate Procedure 32(a)(7)(B)(i) and Federal Circuit Rule 32(b).

1. Exclusive of the exempted portions of the brief, as provided in Federal Rule of Appellate Procedure 32(a)(7)(B) and Federal Circuit Rule 32(b), the brief contains 13,330 words.

2. This brief has been prepared in proportionally spaced typeface using Microsoft Word 2010 in 14 point Times New Roman font. As permitted by Federal Rule of Appellate Procedure 32(a)(7)(B), the undersigned has relied on the word count feature of this Microsoft Word in preparing this certificate, in addition to manually counting and adding the words included in any figures.

Dated: March 23, 2015

/s/ Jason E. Weil
Jason E. Weil

CERTIFICATE OF SERVICE

I hereby certify that I filed the foregoing Brief for Appellant with the Clerk of the United States Court of Appeals for the Federal Circuit via the CM/ECF system this 23 day of March, 2015, and served a copy on counsel of record by the CM/ECF system and by electronic mail.

Dated: March 23, 2015

/s/ Jason E. Weil
Jason E. Weil